Stephen M. Orlofsky
Nicholas C. Harbist
David C. Kistler
New Jersey Resident Partners
BLANK ROME LLP
A Pennsylvania LLP
301 Carnegie Center, 3rd Floor
Princeton, NJ 08540
Telephone: (609) 750-7700

FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PLAINTIFF UNDER SEAL v. DEFENDANTS UNDER SEAL	Civil Action No.: 3:11-cv-6476 **FILED UNDER SEAL** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* JKJ PARTNERSHIP 2011 LLP, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, Registered Office: 3500 S. DuPont Highway Dover, DE 19901 *Plaintiffs*, v. SANOFI-AVENTIS U.S. LLC 55 Corporate Drive Bridgewater, NJ 08807; and SANOFI-AVENTIS U.S. INC. 55 Corporate Drive Bridgewater, NJ 08807; and	Civil Action No.: 3:11-cv-6476 **FILED UNDER SEAL** **FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT AND STATE LAW COUNTERPARTS** **FILED BY HAND** **JURY TRIAL DEMANDED**

AVENTIS INC.
3711 Kennett Pike
Greenville, PA 22002; and

AVENTIS PHARMACEUTICALS, INC.
55 Corporate Drive
Bridgewater, NJ 08807; and

BRISTOL-MYERS SQUIBB
345 Park Avenue
New York, NY 10154; and

BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP
55 Corporate Drive
Bridgewater, NJ 08807

and

345 Park Avenue
New York, NY 10154; and

JOHN DOES #1-50, FICTITIOUS NAMES,

Defendants.

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FIRST AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America by JKJ PARTNERSHIP 2011 LLP ("Relator"), by and through its attorneys, against Defendants Sanofi-aventis U.S. LLC, Sanofi-aventis U.S. Inc., Aventis Inc., Aventis Pharmaceuticals Inc., Bristol-Myers Squibb, Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, and John Does #1-50, Fictitious Names, pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* and pursuant to the *qui tam* provisions of the following States: the California False Claims Act, Cal. Gov't Code § 12650 *et seq.* (Deering 2000); the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 *et seq.*(2010); the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.* (2010); the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 *et seq.* (2000); the District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.* (2000); the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.* (2000); the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.* (2007); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.* (2006); the Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.* (2000); the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.* (2007); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.* (2006); the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-601 *et seq.* (LexisNexis 2010); the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq.* (2007); the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.* (2007); the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.* (2011); the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.* (1999); the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.* (2007); the New Jersey False Claims Act, N.J.

Stat. Ann. § 2A:32C-1 *et seq.* (West 2007); the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (2007); the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.* (McKinney 2010); the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.* (2010); the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.* (2007); the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.* (2008); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* (2006); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.* (West 2006); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* (2011); and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.* (2007) ("State *Qui Tam* statutes" or "*Qui Tam* States").

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States and the *Qui Tam* States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees or co-conspirators under the Federal False Claims Act and the State *qui tam* statutes.

2. Defendants are companies and individuals that manufacture, market, and sell a variety of drugs for medicinal purposes. Beginning at least in 2006, Defendants have engaged in a variety of fraudulent activities, including: (i) illegally promoting the off-label use of Plavix®, an anti-platelet drug; (ii) failing to disclose adverse efficacy data regarding Plavix® despite a legal obligation to do so; and (iii) providing illegal kickbacks and violating the Medicaid Best Price Drug Rebate Program as to both the osteoarthritis drug Hyalgan® and the prostate cancer drug Eligard®.

3. Plavix® is an anti-platelet drug that was approved by the Food and Drug Administration ("FDA") in 1997 as mono-therapy in place of aspirin for the reduction of

atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease. Several years later Plavix® was approved for the treatment of patients suffering from acute coronary syndrome. Acute coronary syndrome (ACS) can be loosely defined as a spectrum of clinical disease in patients who have an acute decrease in blood supply to a region of the heart muscle due to the rupture of a coronary artery plaque and the formation of a blood clot in the vessel. If the vessel remains patent the patient has ACS/unstable angina. If the vessel remains patent but there is embolization of clot down the vessel the patient has ACS/ non-ST segment myocardial infarction (NSTEMI) and if the vessel becomes occluded with blood clot the patient has ACS/ST-segment elevation MI (STEMI).

4. Plavix® received additional FDA approval for the treatment of patients presenting with acute coronary syndrome (ACS) with unstable angina or with non-ST segment myocardial infarction (NSTEMI) based on the results of the CURE trial which demonstrated the superiority of aspirin and Plavix® versus aspirin alone in reducing cardiovascular events. *See* The Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators, *Effects of Clopidogrel in Addition to Aspirin in Patients With Acute Coronary Syndromes Without ST-Segment Elevation*, N. ENGL. J. MED. 345:494-502 (2001) (the "CURE trial"). Plavix® subsequently received further approval for the treatment of ACS/STEMI based on the CLARITY and COMMIT trials. *See* M.S. Sabatine et al., *Addition of Clopidogrel to Aspirin and Fibrinolytic Therapy for Myocardial Infarction with ST-Segment Elevation*, N. ENGL. J. MED. 352:1179-1189 (2005) (the "CLARITY trial"); COMMIT Collaborative Group, *Addition of clopidogrel to aspirin in 45,852 patients with acute myocardial infarction: randomized placebo-controlled trial*, THE LANCET 366:1607-1621 (2005) (the "COMMIT trial"). Those four

"indications" remain the only situations in which Plavix® is FDA-approved for use in treating patients with atherosclerotic coronary artery disease. Notwithstanding the limitations of the FDA approval for Plavix®, Defendants devised and deployed a fraudulent marketing scheme that was intended to (and did) systematically and illegally promote Plavix® "off-label" for treatment of: (i) patients who have undergone a coronary artery bypass graft; (ii) patients who suffer a stroke, transient ischemic attack or any cerebrovascular event; (iii) primary prevention of cardiovascular events in patients at risk; (iv) as part of diagnostic catheterizations in patients who have not suffered an acute coronary event; and (v) specific sub-populations. This off-label promotion scheme has been driven, at least in part, by unrealistic quotas that increase seven percent each year, which the Defendants have placed on their sales representatives, essentially requiring that managers direct the sales force to promote and sell the drug beyond its FDA-approvals, and essentially requiring the sales force to comply.

5. Additionally, the Sanofi Defendants failed to disclose material adverse efficacy data regarding Plavix®, as required by 21 C.F.R. § 314.80 (governing post-marketing reporting of adverse drug experiences), causing physicians to prescribe, and Government Programs to reimburse, Plavix® for millions of patients who were genetically predisposed to experience diminished or no responsiveness to Plavix®, rendering it little more than a placebo and placing the patients at significant risk.

6. Hyalgan® was approved by the FDA in May of 1997 for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics, such as acetaminophen. The Sanofi Defendants directed their sales representatives to use free, trade-size samples of Hyalgan® syringes as an incentive to persuade healthcare providers either to switch their patients to Hyalgan® from

competing brands (*e.g.*, Euflexxa® and Supartz®) or, for current customers, to continue using Hyalgan®. To further the fraud, the Sanofi defendants instructed their sales representatives to promote the "value" of the free, trade-size samples.

7. In addition, the Sanofi Defendants have directed their sales representatives to take advantage of the unique reimbursement aspect of Hyalgan® as a "buy and bill" injectable drug and specifically promote it to physicians as a separate and distinct means of generating income. The Sanofi Defendants recognized the revenue stream available to their customers and encouraged their representatives to "market the spread" – *i.e.*, the difference between the reimbursement rate of the federal health care programs and the actual price paid by health care providers. The larger the spread on a drug, the larger the profit or "return on investment" for the provider.

8. Specifically, over the years, the Sanofi Defendants have set and controlled the price at which Medicare reimburses physicians for Hyalgan® by reporting an inflated average selling price ("ASP"). The ASP reported by the Sanofi defendants has been significantly higher than the sales price the company actually offered to physicians and its other customers. In the case of injectable drugs like Hyalgan®, the ASP is the key metric used to determine how much the Government Programs will reimburse for each prescription. Any unreported discounts would lower the ASP, causing the Government Programs to pay an artificially inflated price to physicians who buy and bill for the Sanofi Defendants' drugs.

9. In these ways, the Sanofi Defendants' promotion of Hyalgan® is characterized by the knowing and willful payment of things of value to influence physicians to prescribe Hyalgan® for their patients, and thus influence federal health care program business.

10. Eligard® is a prescription drug, given by injection, for the palliative treatment of advanced prostate cancer. Eligard® initially was approved by the FDA for this lone indication in January 2002, but additional dosages and concentrations were approved thereafter. As with Hyalgan®, the Sanofi Defendants directed their sales representatives to "market the spread" of Eligard® in order to gain additional market share, particularly with large buying groups. They also used speaker programs and other monetary incentives to encourage and reward "key opinion leaders" who agreed to promote and prescribe Eligard® off-label. In these ways, the Sanofi defendants' promotion of Eligard® is characterized by the knowing and willful payment of things of value to influence physicians to prescribe Eligard® for their patients, and thus influence federal health care program business.

11. Defendants' illegal, off-label promotion of Plavix® has caused hundreds of thousands of false claims to be submitted to federal and state healthcare programs throughout the United States. Defendants' misconduct cheated the federal and state governments out of hundreds of millions of dollars that should not have been paid, thereby illegally enriching the company at taxpayer expense, and subjecting patients to unapproved, ineffective and unsafe uses of Plavix®.

12. The Sanofi Defendants' use of "free" trade-size sample syringes of Hyalgan® to induce physicians to purchase the drug and then bill Government Programs for their use on patients has resulted in millions a year in fraudulent billing. And the company's scheme to market the spread for both Hyalgan® and Eligard® is also resulting in millions of dollars in fraud against Federal programs.

13. Most troubling is the fact that Aventis Pharmaceuticals Inc., a wholly-owned U.S. subsidiary and/or affiliate of the other Sanofi Defendants, already is under a Corporate Integrity

Agreement ("CIA") related to its September 10, 2007 settlement with the Federal Government in which the pharmaceutical company agreed to pay $190 million to settle False Claims Act allegations concerning its pricing and marketing of Anzemet®, an antiemetic drug used primarily in conjunction with oncology and radiation treatment to prevent nausea and vomiting. The Federal Government there alleged that the Sanofi defendants had engaged in a scheme to set and maintain fraudulent and inflated prices for Anzemet®, knowing that federal health care programs established reimbursement rates based on those prices. As part of its 2007 settlement, and in accordance with the CIA that went into effect in August 2007, the company has had to implement stringent controls for five years to ensure that practices such as off-label promotion and fraudulent pricing schemes for its drugs would cease immediately. Despite their agreement with the Government, the Sanofi Defendants have elected to continue their illegal activities at a considerable cost to federal taxpayers and federal programs.

14. At all relevant times, the Defendants have known that Plavix®, Hyalgan® and Eligard® are being paid for or reimbursed by Government Programs, including Medicaid and Medicare Parts B and D.

15. Defendants knew that their conduct described herein would lead to the submission of claims for reimbursement by Government Programs that were not eligible for reimbursement. But for Defendants' illegal conduct, those prescriptions would not have been written. As a result, Defendants have caused, and continue to cause, the submission of false claims to Government Programs, and they have benefited from those the payment of those false claims.

II. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331 and 28 U.S.C. § 1345. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws

for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.

17. This Court has personal jurisdiction over the Defendants because, among other things, the Defendants transact business in this judicial district, and engaged in wrongdoing in this judicial district.

18. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). The Defendants transact business within this judicial district, and acts proscribed by 31 U.S.C. § 3729 occurred in this judicial district.

19. The causes of action alleged herein are timely brought because, among other things, of efforts by the Defendants to conceal from the United States their wrongdoing in connection with the allegations made herein.

III. PARTIES

A. PLAINTIFF/RELATOR JKJ PARTNERSHIP 2011 LLP

20. Plaintiff/Relator, a Delaware general partnership, is named JKJ PARTNERSHIP 2011 LLP and brings this action on behalf of itself, the United States of America and the *Qui Tam* States named herein. The three partners/owners of the partnership are "Partner A", "Partner B" and "Partner C."

21. Pursuant to Section 15-201(a) of the Delaware Revised Uniform Partnership Act, JKJ PARTNERSHIP 2011 LLP is not distinct from its partners, who have personal knowledge of the aforesaid false claims, statements, concealments, and receipts.

22. Partner A has been employed by the Sanofi Defendants since 2003 and has extensive personal knowledge and experience regarding Defendants' sales promotion activities, including personal contact with the employees and executives who have committed violations of law alleged herein. Partner A has observed numerous instances of illegal conduct by the Sanofi

Defendants, including "marketing the spread" (resulting in false reports of ASP and Best Price), providing illegal kickbacks to healthcare providers in exchange for their favorable treatment of the company's products, and promoting drugs for uses the FDA has not provided approval. Partner A no longer works in the division that promotes medication for human patients; instead, she now works in a division focused on veterinary medication.

23. Partner B is an interventional cardiologist in practice in the State of New York who has extensive personal knowledge and experience regarding Defendants' sales promotion activities for Plavix®, including personal contact with employees who have committed violations of law alleged herein. Partner B has regularly been retained and paid by Defendants to deliver promotional sales talks on behalf of Plavix®. Partner B has extensive knowledge regarding the science behind allegations herein that the Sanofi Defendants wrongfully failed to disclose certain material and adverse efficacy data regarding Plavix®. Partner B does not have knowledge regarding the allegations contained herein regarding Hyalgan® and Eligard®.

24. Partner C is a consultative/non-invasive cardiologist in practice in the State of New York who has extensive personal knowledge and experience regarding Defendants' sales promotion activities for Plavix®, including personal contact with employees who have committed violations of law alleged herein. Partner C is one of the highest volume prescribers of Plavix® in the United States, and Defendants have regularly promoted Plavix® to him for both on- and off-label uses. Partner C is knowledgeable regarding the science behind allegations herein that the Sanofi Defendants wrongfully failed to disclose certain material and adverse efficacy data regarding Plavix®. Partner C does not have knowledge regarding the allegations contained herein regarding Hyalgan® and Eligard®.

25. Prior to filing this First Amended Complaint, Partner A brought certain of the allegations of wrongdoing described herein, *i.e.* those relating to the improper promotion of Plavix®, Hyalgan® and Eligard®, to the attention of the Sanofi Defendants by repeatedly raising these concerns with various supervisors, including Todd Keirns (Hyalgan®/Eligard® Manager for Sanofi), Michael Bellotto (Hyalgan®/Eligard® Manager for Sanofi), and Phil Becker (Hospital Manager for Sanofi/Plavix®). For his part, Becker told Partner A to contact the Corporate Compliance Hotline with the concerns, and Partner A did.

26. Among the concerns that Partner A brought to the attention of Phil Becker was her specific complaint that she and hospital sales representative Valerie Madar observed senior specialty sales representative Isabelle Bibet-Kalinyak (who generally called on neurologists, cardiologists and internists in the Akron/Canton, Ohio area) proactively promote off-label use of Plavix® (*e.g.*, for the prevention of stroke in patients with atrial fibrillation) to Dr. Les Tobias of the Cardiac Cath Lab at Akron General Medical Center in August 2008. Partner A told Becker that she was verbally scolded by Bibet-Kalinyak when she challenged her obvious misconduct, and that Bibet-Kalinyak criticized her for not being interested in increasing sales. Becker showed little interest in the issue. When Partner A later complained to Mr. Becker that she had observed Bibet-Kalinyak violate other compliance rules (*e.g.*, permitting physicians' spouses to attend speaker/dinner programs, and inviting physicians to lunch outside their offices), he responded only that he "could talk to [Bibet-Kalinyak's] manager" if Partner A wanted him to, but that Ms. Bibet-Kalinyak had a "great reputation" within the company, and that her manager and "corporate" thought very highly of her. He implied that he did not want to deal with Partner A's complaints. Valerie Madar made a similar report to her manager, Gina Fortunato, who similarly dismissed her concern on the bases that Bibet-Kalinyak had a "great reputation" within

the company, and that she "highly doubt[ed]" that Bibet-Kalinyak had done anything wrong. In this manner, Defendants' managers, Becker and Fortunato, dismissed Partner A's concerns as unimportant. Partner A was persistent, and she reported Bibet-Kalinyak's misconduct to the Sanofi Defendants' human resources department, but Bibet-Kalinyak received only a slap on the wrist.

27. By way of further example, Sanofi sales representative John Anthony ("Tony") Poelking, who also worked under the supervision of Phil Becker, reported to Becker that another sales representative, Ken Post, was making "homemade bread" – a term used by the sales force to denote the creation of unapproved sales pieces. Partner A is not aware of any disciplinary action that was taken against Mr. Post for his misconduct.

28. In hindsight, Partner A is not aware of a single instance in which a sales representative was fired for initiating or failing to report illegal activities, though Partner A repeatedly observed such conduct among her sales representative colleagues. (Ms. Bibet-Kalinyak was terminated in late 2010 as part of company-wide layoffs. Mr. Poelking was terminated in 2009, but Mr. Post remains employed by Sanofi.)

29. Partner A, Partner B and Partner C are original sources of the allegations in this First Amended Complaint, and these allegations are not based upon publicly disclosed information. Partner A, Partner B and Partner C have, through Plaintiff/Relator, provided the Government with material information prior to the filing of this First Amended Complaint in accordance with 31 U.S.C. § 3730(b)(2), including myriad documents and a preliminary disclosure statement.

B. **DEFENDANT SANOFI-AVENTIS**

30. Defendant Sanofi-aventis U.S. LLC is a Delaware limited liability company with headquarters and research facilities located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

31. Defendant Sanofi-aventis U.S. Inc. is a Delaware corporation with offices located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

32. Defendant Aventis Pharmaceuticals Inc. is a Delaware corporation with offices located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

33. Defendant Aventis Inc. is a Pennsylvania corporation with offices located at 3711 Kennett Pike, Greenville, Pennsylvania 22002.

34. Defendants Sanofi-aventis U.S. LLC, Sanofi-aventis U.S. Inc., Aventis Inc. and Aventis Pharmaceuticals Inc. (collectively referred to herein as "Sanofi" or the "Sanofi Defendants") are wholly-owned U.S. subsidiaries of Sanofi-aventis, a holding company of a consolidated group of subsidiaries that engage in research and development, manufacturing, and marketing of pharmaceutical products for sale principally in the prescription market. The U.S. headquarters of Sanofi-aventis, and the location from which its U.S. activities are directed, is 55 Corporate Drive, Bridgewater, New Jersey 08807. Among the products marketed by Sanofi-aventis are the anti-platelet drug Plavix®, the osteoarthritis drug Hyalgan®, and the prostate cancer drug Eligard®.

35. As described more fully herein, Sanofi is engaged in the manufacture, promotion, distribution, commercialization and sale of products for, among other things, oncology therapies. At all times material hereto, Sanofi marketed and sold a range of brand pharmaceuticals and consumer medicines, including the drugs Plavix®, Hyalgan®, and Eligard®, throughout the United States, including within this judicial district.

36. Sanofi markets and sells, and marketed and sold, brand-name prescription drug products, including Plavix®, Hyalgan®, and Eligard®, that are paid or reimbursed by various government programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits program under a prime contract with the Blue Cross Blue Association, the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395, *et seq.*, via Medicare Part C, (also known as Medicare+Choice), Medicare Part B, Medicare Advantage, the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan, the U.S. Secret Service Employees Health Association Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE") and the Veteran's Health Administration ("VHA") (collectively, the "Government Programs").

37. As a result of Sanofi's actions, the *Qui Tam* States and Government Programs have suffered significant financial harm.

C. **DEFENDANT BRISTOL-MYERS SQUIBB**

38. Defendant Bristol-Myers Squibb Company ("BMS") is a Delaware corporation with its principal corporate offices at 345 Park Avenue, New York, New York and facilities located throughout the State of New Jersey. At all times material hereto, BMS marketed and sold a range of brand pharmaceuticals and consumer medicines, including Plavix®, throughout the United States, including within this judicial district.

39. BMS markets and sells, and marketed and sold, brand-name prescription drug products, including Plavix®, which are paid or reimbursed by various government programs, including the Government Programs.

40. BMS knowingly contributed its employees and other resources to perpetuation of the Fraudulent Marketing Scheme described in this First Amended Complaint, though it directed

the members of its sales force to identify themselves not as "BMS representatives" but rather as "Plavix® representatives." Indeed, BMS sales representatives and Sanofi sales representatives often conduct joint sales calls on health care providers.

41. As a result of BMS' actions, the *Qui Tam* States and Government Programs have suffered significant financial harm.

D. DEFENDANT BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP

42. Defendant Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership a/k/a Bristol Myers Squibb/Sanofi-Synthelabo Partnership ("the BMS/Sanofi Partnership") is a partnership that is jointly operated by Sanofi and BMS through their facilities throughout the United States and in this judicial district in order to promote the sale of Plavix® throughout the United States and in this judicial district.

43. The BMS/Sanofi Partnership markets and sells, and marketed and sold, brand-name prescription Plavix® that is paid or reimbursed by various governmental programs, including the Government Programs.

44. Sanofi and BMS knowingly contributed their employees and other resources to the perpetuation of the Fraudulent Marketing Scheme described in this First Amended Complaint through the form of the BMS/Sanofi Partnership. However, when their sales representatives call upon health care providers for the purpose of promoting Plavix®, they distribute business cards that identify themselves as representatives of either "sanofi aventis" or "sanofi-synthelabo" or "Bristol-Myers Squibb Company," thus plainly implicating all the defendants in their misconduct.

45. As a result of the BMS/Sanofi Partnership's actions, the *Qui Tam* States and Government Programs have suffered significant financial harm.

IV. SUMMARY OF DEFENDANTS' ILLEGAL CONDUCT

A. THE FRAUDULENT MARKETING SCHEME

46. It was the plan and purpose of Defendants' fraudulent marketing scheme to illegally promote Plavix® for uses not approved by the FDA (hereinafter, the "Fraudulent Marketing Scheme"). The objective of the Fraudulent Marketing Scheme was to increase sales of Plavix®, and Defendants implemented the Fraudulent Marketing Scheme in two ways.

47. First, Sanofi intentionally suppressed adverse efficacy data that demonstrates upwards of 30% of patients treated with Plavix® will experience diminished or no responsiveness at all. When this information became widely known through other channels, Defendants sought to mitigate the potential impact on sales by proactively encouraging doctors to prescribe *higher* doses of the drug to patients with diminished responsiveness, even though such dosing is not approved by the FDA.

48. Second, Defendants trained, directed and deployed their substantial combined sales force to illegally promote Plavix® for unapproved uses and therapies in lieu of less expensive approved therapies. Defendants intended that their Fraudulent Marketing Scheme would cause false and fraudulent statements and claims for payment to be submitted to Government Programs. That is what occurred, permitting Defendants to maximize profits through ill-gotten gains.

49. The Fraudulent Marketing Scheme was designed and deployed in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, and its state analogues.

50. Defendants' unlawful off-label promotion of Plavix® involved the unlawful making of false records or statements and/or causing false claims to be submitted for the purpose of getting the false records or statements to bring about the Federal Government and *Qui Tam* States' payment of false or fraudulent claims. As described herein, these false records, statements

and claims related to claims for reimbursement by Government Programs of prescriptions for Plavix® that were induced by false and misleading promotional practices, and prescriptions that related to off-label uses of the drug.

51. Defendants' conduct had a material effect on the Federal Government and *Qui Tam* States' decision to pay for Plavix®. Had the Federal Government and *Qui Tam* States known that the off-label prescriptions were the direct and intended result of Defendants' unlawful activities, they would not have made such reimbursements, or they would have reimbursed substantially lesser amounts.

52. It further was part of the Fraudulent Marketing Scheme that Defendants attempted to conceal and cover up the off-label marketing of Plavix®.

53. The Fraudulent Marketing Scheme is ongoing.

B. **THE ILLEGAL KICKBACK SCHEME**

54. It was the plan and purpose of Sanofi's Fraudulent Kickback Scheme to: (i) provide free, trade-size "samples" of Hyalgan® to physicians in exchange for their commitment to purchase commercial Hyalgan® in the future; (ii) induce physicians to prescribe Hyalgan® and Eligard® based on the "spread" between what they would pay to purchase the drug, and what they would ultimately be reimbursed by federal health care programs and private insurers to prescribe it; and (iii) use speaker programs and other monetary incentives to encourage and reward "key opinion leaders" to prescribe Hyalgan® and Eligard® (hereinafter, the "Fraudulent Kickback Scheme"). These actions violated the Federal Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b(b), because they were taken to induce customers to buy Sanofi's drug products.

55. The exchange of free drug samples for agreements to purchase future Sanofi drugs also violates the Prescription Drug Marketing Act of 1987 (the "PDMA"), which prohibits the sale, purchase or trade of drug samples.

56. These kickbacks were intended to result in the dispensing of Sanofi's drugs, including, but not limited to, Hyalgan® and Eligard®, and subsequent reimbursement by Sanofi's customers, including its Government Program customers.

57. The payment and receipt of these kickbacks resulted in increased expense to Government Program customers in as much as Sanofi's brand name products were more expensive than the cheaper generic equivalents.

58. Sanofi's provision of free Hyalgan® drug samples to its customers was made knowingly and with the intent to induce Government Program payments for Sanofi's drug products through a pattern of corrupt and illegal conduct.

59. Sanofi's conduct underlying the Fraudulent Kickback Scheme was made in violation of the AKA, the PDMA, and the federal and state False Claims Acts.

C. **THE MEDICAID BEST PRICE SCHEME**

60. Sanofi's scheme to provide free Hyalgan® samples to induce the purchase of its product Hyalgan® implicates the Medicaid Best Price Drug Rebate Program. When Sanofi provides free samples of Hyalgan® to physicians in an effort to induce them to prescribe more of the drug, the company is required to account for the value of the free samples when it calculates and then reports its quarterly Best Price reports to state Medicaid programs. The company has failed to do so.

61. The impact of even one such "free" sample in any quarter would, by implication, create a Medicaid Best Price of $0 per syringe for that quarter, compared to the approximately $80 per syringe that Sanofi-aventis would have reported.

62. Because Sanofi intentionally reported false Best Prices for Hyalgan®, it wrongfully failed to pay accurate quarterly rebates to each state during each applicable rebate period. And, consequently, Sanofi wrongfully over-charged Section 340B Program participants and the Veteran's Administration for its drugs, and it retained such overpayments.

63. Sanofi knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government. Specifically, for the period noted above, and continuing through the present, Sanofi knowingly (or in reckless disregard of the truth) submitted false quarterly statements to the Centers for Medicare and Medicaid Services ("CMS") of its Best Prices on Hyalgan® to reduce improperly its rebate obligation to the States under the Best Price Program.

64. Sanofi's false quarterly statements of its Hyalgan® Best Price caused the States to submit false and inflated submissions to the Federal Government for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2).

V. BACKGROUND OF THE REGULATORY FRAMEWORK

A. THE FOOD AND DRUG ADMINISTRATION ("FDA") REGULATORY SYSTEM

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

65. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

66. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

67. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. *See* 21 U.S.C. § 321. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness. *See* 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *See* 21 U.S.C. §§ 355(d)(1), (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *See* 37 Fed. Reg. 16,503 (1972).

68. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (i) clear objectives; (ii) adequate design to permit a valid comparison with a control group; (iii) adequate selection of study subjects; (iv) adequate measures to minimize bias; and (v) well defined and reliable methods of assessing subjects' responses to treatment. *See* 21 C.F.R. § 314.26.

69. The FDA has addressed the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 *Guidance to the Industry*, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products*, May 1998. *See, e.g.,* Final Decision on Benylin, 44 Fed. Reg. 51,512 (Aug. 31, 1979). The FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962). Nevertheless, the FDA has been flexible within the limits imposed by the Congressional scheme, broadly interpreting the statutory requirements to the extent possible where the data on a particular drug was convincing. In some cases, the FDA has relied on pertinent information from other adequate and well-controlled studies of a drug, such as studies of other doses and regimens, of other dosage forms, in other stages of disease, in other populations, and of different endpoints, to support a single adequate and well-controlled study demonstrating effectiveness of a new use. In these cases, although there is only one study of the exact new use, there are, in fact, multiple studies supporting the new use, and expert judgment could conclude that the studies together represent substantial evidence of effectiveness.

70. In other cases, the FDA has relied on only a single, adequate and well-controlled efficacy study to support approval – generally only in cases in which a single multicenter study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds. In section 115(a) of the Modernization Act, Congress amended section 505(d) of the Act to make it clear that the Agency may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed the FDA's interpretation of the statutory requirements for approval and acknowledged the Agency's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

71. Cases in which the FDA has approved a drug on the basis of one clinical trial plus confirmatory evidence are rare. They include instances of large, independently conducted multicenter trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

72. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect

the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

2. FDA Regulations Prohibit Off-Label Marketing and False and Misleading Statements about a Drug's Use.

73. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels – including all marketing and promotional materials relating to the drug – may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

74. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks, as well as the benefits, be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

75. A manufacturer, like Sanofi, wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new

indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

76. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, *e.g.,* treating a child when the drug is approved to treat adults.

77. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his or her condition, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trial evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored continuing medical education ("CME") courses and speaker programs, and drug company sponsored clinical trials.

78. Although physicians may prescribe drugs for off-label use, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the

drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

79. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. § 202.1, as well as the FDA's "fair balance" requirement, described below.

80. Title 21 of the Code of Federal Regulations provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." 21 C.F.R. § 202.1(e)(6)(xi); *see also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331(a) (prohibiting distribution of a misbranded drug); *id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

81. The FDA regulations that fall under the general rubric of 21 C.F.R. § 202.1(e)(6) *et seq*. ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. *See* 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Thus, companies such as Sanofi may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as more safe or more effective

than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Government Programs, including Medicaid.

82. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." *See* 21 C.F.R. § 202.1(e)(6)(iv).

83. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *See* 21 C.F.R. § 202.1(e)(5) *et seq*. A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

84. Title 21 of the Code of Federal Regulations broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug. 21 C.F.R. § 202.1(l)(2)

85. Title 21 also requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." 21 C.F.R. § 201.56.

86. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

87. These regulations lay out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. 21 C.F.R. § 99.101 *et seq.* This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. § 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." *Id.* § 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. *Id.* § 99.101(b)(2).

88. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." *Id.* § 99.101(a)(4).

89. And off-label information may be disseminated only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa(b), (c); *id.* § 360aaa-1.

90. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. And the prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

B. THE ROLE OF THE COMPENDIA

91. Congress has adopted a Compendia-based system for determining appropriate Medicaid reimbursements for off-label uses of a "covered outpatient drug." *See* Social Security Act §§ 1927(g)(1)(B)(i), (k)(6). The statute permits reimbursements for drug uses that "(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."

92. Thus, the only way a prescription for an off-label use could be reimbursed under Medicaid, Medicare or the other federal reimbursement programs is if the particular off-label use was approved by one of the compendia identified in the Social Security Act, such approval qualifying the use as a "medically accepted indication." The leading non-oncology compendia are Thomson Micromedex DrugDex ("DrugDex") and the American Hospital Formulary Service Drug Information ("AHFS").

93. It merits emphasis that even where an off-label use is supported by the Compendia, drug companies may not legally promote that use to healthcare professionals or patients.

C. FEDERAL HEALTH CARE PROGRAMS AND OTHER GOVERNMENT PROGRAMS

1. The Medicaid Program

94. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared

between the Federal Government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

95. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the Federal Government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2)-(3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* § 1396r-8(k)(3).

96. A medically-accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that is included in one of the drug Compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6); *see* discussion *supra*. During the time period relevant to this First Amended Complaint, Defendants promoted off-label uses of Plavix® that were not eligible for reimbursement from Medicaid because the off-label uses were neither listed in the FDA-approved labeling nor adequately supported by the effective drug Compendia specified by the Medicaid statute.

2. The Medicare Program

97. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

98. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k), as described above.

99. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

100. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004, and again for 2005.

101. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies.

102. During the time period relevant to this First Amended Complaint, Defendants promoted off-label uses of Plavix® that were not eligible for reimbursement from Medicare because the off-label uses were neither listed in the FDA-approved labeling nor adequately supported by the effective drug Compendia specified by the statute.

3. Reimbursement Under Other Federal Health Care Programs

103. In addition to Medicaid and Medicare, the Federal Government reimburses a portion of the cost of prescription drugs under several other federal health care programs. For example:

(i) CHAMPUS/TRICARE is a health care program administered by the Department of Defense for individuals and dependants affiliated with the armed forces.

(ii) CHAMPVA is a health care program administered by the Department of Veterans Affairs for families of veterans with 100% service-connected disabilities.

(iii) The Federal Employee Health Benefit Program provides health insurance for federal employees, retirees and survivors, and it is administered by the Office of Personnel Management.

Coverage of off-label drug use under these programs is similar to the coverage provided by the Medicaid program. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B)

(2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

104. When a healthcare provider seeks reimbursement from Medicare, it first identifies the particular reimbursement code for the drug prescribed. These reimbursement codes are a component of the CMS Healthcare Common Procedure Coding System ("HCPCS"). The HCPCS is designed to bill for drugs that are utilized in the physician's office, clinic or home health agency. Under this classification scheme, most covered drugs are assigned J-codes, which are permanent codes used to identify injectable drugs that ordinarily cannot be self-administered, as well as some oral anti-cancer drugs. The J-Code for Eligard® is J9217 and the J-Code for Hyalgan® is J7321.

105. Plavix® and Eligard® can also be dispensed at pharmacies for patients with a prescription. Pharmacies seek reimbursement from Medicare based on a drug's National Drug Code ("NDC") number.

106. The NDC codes for Plavix® are:

Package Configuration	Tablet Strength	NDC Code	Imprint
Bottles of 30	75 mg	NDC 63653-1171-6	1171 & 75
Bottles of 90	75 mg	NDC 63653-1171-1	1171 & 75
Blisters of 100	75mg	NDC 63653-1171-3	1171 & 75
Bottles of 500	75 mg	NDC 63653-1171-5	1171 & 75
Unit-Dose Packages of 30	300 mg	NDC 63653-1332-2	1332 & 300
Unit-Dose Packages of 100	300 mg	NDC 63653-1332-3	1332 300

107. The NDC codes for Eligard® are:

Formulation	Needle Gauge	Needle Length	NDC Code

Formulation	Needle Gauge	Needle Length	NDC Code
Eligard® 7.5 mg	20-gauge	½ inch	NDC 0024-0793-75
Eligard® 22.5 mg	20-gauge	½ inch	NDC 0024-0222-05
Eligard® 30 mg	20-gauge	5/8 inch	NDC 0024-0610-30
Eligard® 45 mg	18-gauge	5/8 inch	NDC 0024-0605-45

VI. BACKGROUND OF PLAVIX®, HYALGAN® AND ELIGARD®

A. PLAVIX®

108. Plavix® is an oral tablet formulation of clopidogrel bisulfate that since March 1998 has been exclusively marketed in the United States by Defendants, through the BMS/Sanofi Partnership, under the registered trademark "Plavix®."

109. Plavix® was first approved by the FDA on November 17, 1997 for the reduction of atherosclerotic events (myocardial infarction, stroke and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction or established peripheral arterial disease ("PAD"). Several years later, on February 27, 2002, the FDA approved Plavix® for the treatment of patients with Acute Coronary Syndrome (unstable angina/non-ST-elevation myocardial infarction) – also known as "NSTEMI." And on August 17, 2006, the FDA approved Plavix® for the treatment of patients with Acute Coronary Syndrome (ST-elevation myocardial infarction) – also known as "STEMI."

110. As indicated, Government Programs are permitted to reimburse the off-label (*i.e.*, non-FDA-approved) use of Plavix® if the use in question has the necessary Compendia support, and if such use was not prompted by some false or misleading promotion by Defendants. Ten uses of Plavix® find support in the relevant Compendia:

Indication	FDA Approved	Compendium
Percutaneous coronary intervention, elective – Thrombosis; Prophylaxis	No	Adult; Class IIa (DrugDex)
Acute ST-segment elevation myocardial infarction – Percutaneous coronary intervention – Thrombosis; Prophylaxis	No	Adult, Class IIa (DrugDex)
		AHFS
Atrial fibrillation – Thrombosis; Prophylaxis	No	Adult; Class IIb (DrugDex)
Chronic heart failure – Thrombosis; Prophylaxis	No	Adult; Class IIb (DrugDex)
Stasis ulcer	No	Adult; Class IIb (DrugDex)
Cardiac Surgery for congenital heart disease with placement of a systemic-to-pulmonary shunt or stent	No	Neonates, infants, and young children (Clinical Pharmacology)
Other cardiac conditions with a risk for arterial thrombosis (*e.g.*, Kawasaki disease)	No	Neonates, infants, and young children (Clinical Pharmacology)
Primary prevention of myocardial infarction	No	AHFS
Chronic stable angina	No	AHFS
Other atherosclerotic and ischemic conditions	No	AHFS

111. It merits emphasis that, although a use may be cited in one of the Compendia, Defendants still were not legally permitted to promote that use.

112. There are potentially serious adverse reactions associated with Plavix®. Its FDA-approved label specifically identifies "[b]leeding, including life-threatening and fatal bleeding" as "the most commonly reported adverse reaction" and it warns that combination use with non-steroidal anti-inflammatory drugs (*e.g.*, Advil®, Aleve®, aspirin) "increases the risk of gastrointestinal bleeding." Today, the FDA label includes a "Black Box" warning that is intended to alert physicians to the drug's diminished effectiveness in poor metabolizers; however, as discussed more fully below, this warning was added to the FDA label only recently. The FDA label also describes post-marketing adverse reactions to Plavix®, including serious

blood and lymphatic system disorders, eye disorders, and gastrointestinal disorders, among others. One publicly available index of reported adverse events related to Plavix® identifies 1,899 reported adverse events primarily between April 2009 and March 2010. *See* http://www.druglib.com/adverse-reactions_side-effects/Plavix®/ (last viewed Oct. 26, 2011). Among those adverse events, 337 resulted in death, 137 resulted in life-threatening events and 815 resulted in hospitalization. *Id.*

113. At Sanofi, the Plavix® sales team included three components: (i) Hospital Representatives who called on both large and small institutions (typically paired two to a region); (ii) Specialty Representatives who promoted to specialists and who supported the Hospital Representatives in the office setting; and (iii) Primary Care Representatives who called on general practitioners and used samples to ensure that patients would stay "on drug." The BMS Plavix® sales team was constructed in similar fashion. There were ten Hospital Representatives in Partner A's district, which was led by District Manager Phil Becker and Regional Manager Mike Loney.

114. As discussed more fully below, Defendants have systematically and deliberately promoted uses of Plavix® that are not approved by the FDA and that are not eligible for reimbursement by Government Programs.

115. And, also as discussed more fully below, Defendants have systematically and deliberately promoted Plavix® through false and misleading advertising that overstates efficacy, advances unsubstantiated superiority claims, and minimizes critical adverse event and risk information. As a consequence, the FDA has issued at least five Warning Letters relating to the promotion of Plavix®. Specifically:

(i) on November 23, 1998, DDMAC notified Sanofi that Defendants' dissemination of a letter, ostensibly authored by a physician, violated the FDCA because it promoted Plavix® for an unapproved use (immediately prior to coronary artery stent placement) and an unapproved dose (300mg loading dose), and because it lacked fair balance in failing to disclose any of the risks associated with the use of Plavix®;

(ii) on December 18, 1998, DDMAC notified Sanofi that multiple promotional materials it disseminated (a brochure, a journal advertisement and a video) contained promotional claims that were false or misleading, and lacking in fair balance, because they made unsubstantiated superiority claims (relative to aspirin), overstated efficacy, and minimized or failed to adequately present adverse event and risk information;

(iii) on June 8, 2001, DDMAC notified Sanofi that its dissemination of a direct-to-consumer television ad for Plavix® was misleading and violated regulatory requirements because it minimized the role of physicians in determining whether Plavix® is the appropriate therapy for the patient's condition, and because it did not fulfill the regulatory requirement for ensuring "adequate provision" for disseminating the approved product labeling;

(iv) on May 9, 2001, DDMAC notified Sanofi that its dissemination of particular visual aid for Plavix® contained false or misleading promotional claims, and violated the FDCA, because it overstated efficacy, included an

unsubstantiated superiority claim (relative to aspirin), and included a misleading efficacy presentation; and

(v) on March 26, 2009, DDMAC notified Sanofi that three "sponsored links" were misleading because they made "representations and/or suggestions about the efficacy of [Plavix®] but fail[ed] to communicate **any** risk information associated with the use of this drug" (emphasis in original), thus suggesting that Plavix® is safer than has been demonstrated.

In sum, Defendants are repeat offenders who consistently, since 1998, have knowingly promoted Plavix® for unapproved uses and doses, and who have misled physicians and patients regarding the drug's efficacy and safety even as the FDA repeatedly warned them against such misconduct.

116. Defendants' motive to repeatedly ignore the law and put patient safety at risk has been money. Plavix® has been a financial blockbuster drug for Defendants. Total U.S. net sales in 2010 alone were $4.7 billion, reflecting a 10.2% increase over 2009. Total U.S. net sales in 2009 were $4.2 billion, reflecting a 11.2% increase over the prior year. Total Medicaid reimbursements for Plavix® between 1998 and the second quarter of 2011 (the last period for which such data is publically available) were approximately $3.8 billion.

B. **HYALGAN®**

117. Hyalgan® is an injected formulation of sodium hyaluronate, which is similar to the fluid that generally surrounds the joints and functions as a lubricant and "shock absorber" for the knee. Since 2000, Hyalgan® has been exclusively marketed and sold in the United States by Sanofi.

118. Hyalgan® was first approved by the FDA on May 28, 1997 for treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (*e.g.*, acetaminophen). The indication has not

been expanded, and no additional uses of Hyalgan® are supported by the Compendia. Thus, approved use of Hyalgan® is quite narrow.

119. Hyalgan® is a physician-administered drug, which means that it can only be administered by a physician in his or her office.

120. Hyalgan® has been a very profitable drug for Sanofi, averaging some $100 million in annual sales. Total reported Medicaid reimbursements for Hyalgan® between the second quarter of 1998 and the fourth quarter of 2007 (the last period for which such data is publicly available) exceeded $2.4 million.

121. Hyalgan® has become something of a commodity drug, as there are many comparable drugs now on the market and none is more effective (or better tolerated) than any other. This has increased pressure on Sanofi sales representatives to use gimmicks and improper inducements to differentiate Hyalgan® from the competition.

122. Further compounding the challenge presented to sales representatives, sales of Hyalgan® have significantly eroded as more physicians, including many of the larger orthopedic practices, have elected to purchase their supplies of Hyalgan® from Canadian distributors, who are able to offer discounts that can exceed 90%.

123. As discussed more fully below, Sanofi has met these challenges, and improperly expanded the market for Hyalgan®, by offering physicians a series of improper financial inducements to prescribe the product. In the process, both patients and Government Programs have been defrauded.

C. **ELIGARD®**

124. Eligard® (leuprolide acetate) is an LHRH (luteinizing hormone-releasing hormone) agonist that is designed to reduce the amount of testosterone in the body by reducing the testicles' production of testosterone. Eligard® is administered by subcutaneous injection,

typically in a physician's office, outpatient clinic or hospital. It is supplied directly to the physician in two separate syringes: one that contains the drug, and a second that contains a polymeric delivery system that allows the drug to be released continuously for the prescribed dosing period. Prior to administering the drug, the physician must manually mix the contents of the two syringes to obtain a uniform suspension that must be administered within thirty minutes of mixing or discarded.

125. Eligard® has been approved by the FDA only for the palliative treatment of advanced prostate cancer, albeit in four different treatment regimens as follows:

DOSAGE	ADMINISTRATION	FDA APPROVAL
7.5mg	Monthly	January 23, 2002
22.5mg	Every three months	July 24, 2002
30mg	Every four months	February 13, 2003
45mg	Every six months	December 14, 2004

126. As indicated, Government Programs are permitted to reimburse the off-label (*i.e.*, non-FDA-approved) use of Eligard® if the use in question has the necessary Compendia support, and if such use was not prompted by some false or misleading promotion by Sanofi. Twenty uses of Eligard® (leuprolide acetate) find support in the relevant Compendia:

Indication	**FDA Approved**	**Compendium**	**Compendia-Supported Doses**
Amenorrhea	No	AHFS	n/a
Amenorrhea – Induction	No	Adult; Class IIb (DrugDex)	7.5mg monthly
Anovulation	No	AHFS	n/a
Benign prostatic hyperplasia (BPH)	No	Clinical Pharmacology	1mg daily 3.75mg monthly

Indication	FDA Approved	Compendium	Compendia-Supported Doses
Breast cancer	No	Adult; Class IIb (DrugDex)	1-10mg daily 3.75mg monthly 11.25mg every 3 months
		AHFS	n/a
		Clinical Pharmacology	3.75mg monthly 11.25mg every 3 months
Breast cancer - Invasive	No	Adult; Category 2A (NCCN Compendium)	n/a
Central precocious puberty	No	Pediatric; Class IIb (DrugDex)	3.75mg monthly 4 to 50mcg/kg daily
		AHFS	n/a
Delayed puberty	No	AHFS	n/a
Endocrine disorders	No	AHFS	n/a
Endometriosis	No	Adult; Class IIa (DrugDex)	1mg daily 3.75mg monthly
Hypogonadism	No	AHFS	n/a
In vitro fertilization / infertility	No	Adult; Class IIb (DrugDex)	0.25-1 mg daily 3.75mg monthly
		Clinical Pharmacology	0.5-1mg daily
Male contraceptive agent	No	AHFS	n/a
Obligospermia	No	AHFS	n/a
Ovarian cancer	No	Adult; Class IIb (DrugDex)	1mg daily 7.5mg monthly
Premenstrual syndrome (PMS)	No	Adult; Class IIb (DrugDex)	3.75mg monthly
		Clinical Pharmacology	0.5-1mg daily

Indication	FDA Approved	Compendium	Compendia-Supported Doses
Prostate cancer	No	Adult; Class IIb (DrugDex)	7.5mg monthly 22.5mg every 3 months
		Adult; Category 2A (NCCN Compendium)	n/a
Prostate cancer – Neoadjuvant treatment	No	Adult; Class IIb (DrugDex)	7.5mg monthly
		Adult; Category 2A (NCCN Compendium)	n/a
Stuttering priapism	No	Clinical Pharmacology	1.3-7.5mg monthly
Uterine Leiomyoma	No	Adult; Class IIb (DrugDex)	0.5mg daily 3.75mg monthly
		AFHS	3.75mg monthly

127. It merits emphasis that many of the Compendia citations listed above support off-label uses of Eligard® in doses (*e.g.*, 3.75mg monthly, or 11.25mg every three months) that are not available on the commercial market because Eligard® is FDA-approved only in doses of 7.5mg, 22.5mg, 30mg and 45mg. Thus, if a physician wanted to prescribe Eligard® for such an off-label use, he or she would be required to manually alter the pre-loaded syringes that are provided by the manufacturer.

128. Use of Eligard® poses significant safety risks. For example, its FDA-approved label warns that during the first few weeks of treatment symptoms may worsen or be accompanied by new symptoms, including bone pain, neuropathy, hematuria, bladder outlet obstruction, ureteral obstruction or spinal cord compression. The FDA-approved label also warns that patients taking Eligard® are at an increased risk of developing diabetes, myocardial infarction, sudden cardiac death, and stroke.

129. Since its initial approval, Eligard® has been exclusively marketed and sold in the United States by Sanofi. In April 2010, the FDA issued a Warning Letter to Sanofi, stating that the company's "6 Month Got Time Patient Profile Piece" misbrands Eligard® because it "omits and minimizes important risks for Eligard, overstates the efficacy, makes misleading presentations, and makes unsubstantiated efficacy and convenience claims for Eligard."

130. As discussed more fully below, Sanofi has illegally promoted sales of Eligard® by: (i) "marketing the spread" – that is, by encouraging physicians (and particularly large buying groups) to prescribe Eligard® not because it is the right treatment regimen for their patients, but because the physicians themselves can earn a significant profit on the "spread" between the cost they pay to purchase the drug from Sanofi-aventis and the amount they will be reimbursed by their patients' insurers, including Government Programs; and (ii) through "Meet the Competition" (MTC) deals and "Just in Time" (JIT) deals, including packages of discounts and "free" services.

131. Eligard® has been a very profitable drug for Sanofi. Worldwide sales of Eligard® totaled $225 million in 2008 and approximately $240 million in 2009. Total Medicaid reimbursements for Eligard® between 2003 and the second quarter of 2011 (the last period for which such data is publicly available) were approximately $8.9 million, with an increasing trend-line.

132. It merits emphasis that because Eligard® is indicated solely for the palliative treatment of advanced prostate cancer, the patient population is disproportionately elderly. Indeed, the majority of patients (approximately 70%) studied in Eligard® clinical trials were age 70 and older. Thus, Sanofi anticipated, and it has been the case, that the majority of patients who have been prescribed Eligard® have been Government Program beneficiaries.

VII. THE FRAUDULENT MARKETING SCHEME

133. The first element of Defendants' Fraudulent Marketing Scheme relates to the deliberate and illegal suppression of adverse efficacy data. Specifically, Sanofi failed to proactively disclose – as the law requires (*see* 21 C.F.R. § 314.80 and discussion *infra*) – adverse efficacy data that demonstrates upwards of 30% of patients treated with Plavix® will experience diminished or no responsiveness at all. When this information became widely known through other channels, Defendants sought to mitigate the potential impact on sales by proactively encouraging doctors to prescribe *higher* doses of the drug (600mg loading doses and 150mg daily) to patients with diminished responsiveness, even though such dosing is not supported in the literature and not approved by the FDA. As explained below, Defendants' conduct in this regard put patients at risk, and caused patients, private insurers and Government Programs to pay significant sums for drugs that offered little more than a placebo effect, if that.

134. The second element of Defendants' Fraudulent Marketing Scheme involves off-label promotion. Although Plavix® is approved by the FDA only for the treatment of three narrowly defined conditions, *see* discussion *supra*, each involving treatment *after* a serious cardiac event already has occurred, Defendants have aggressively promoted and sold the drug off-label for other, generally prophylactic uses as well. In essence, and in utter disregard of the drug's label and risk profile, Defendants have promoted Plavix® as a "wonder drug" that should be widely prescribed for the prevention of a broad array of cardio-vascular ailments even in patients who have not already suffered a serious cardiac event. Indeed, Defendants recently acknowledged in a written "Compliance Message to Plavix® Field Sales" that "recent market research data" had confirmed that sales representatives were promoting Plavix® off-label. Although the "Compliance Message" was accompanied by two slides that articulated examples of "appropriate" and "inappropriate" messaging, a number of these purportedly inappropriate

messages are (or have become), per Partner B and Partner C, actually standard of care in treating their patients. However, even then, there remain clearly inappropriate (*i.e.*, non-standard of care) messages on the slide, including use of Plavix® for the treatment of: (i) peripheral vascular disease; (ii) stroke/Transient Ischemic Attack or any cerebrovascular accident; (iii) acute coronary syndrome with drug-eluting stents; and (iv) primary prevention.

135. This off-label promotion scheme has been driven, at least in part, by unrealistic quotas that Defendants have placed on their sales representatives, essentially requiring that they promote and sell Plavix® *beyond* the limits of its FDA-approval. For example, by 2009, Plavix® was a "mature" drug in most regions of the country, such that it would be unrealistic to expect significant continued growth. The problem is more stark in the case of hospitals, many of which had, by 2010, implemented protocols that recommended *twice* the amount of Plavix® that is specified by the drug's FDA label, such that a sales representative promoting Plavix® to those institutions *could not* achieve sales growth without promoting Plavix® off-label. Defendants referred to this early loading of Plavix® as a "strong start." For example, the protocol at Akron (Ohio) City Hospital recommends loading STEMI/NSTEMI patients with 600mg of Plavix® (as opposed to the 300 mg approved by the FDA), followed with 150mg daily for seven days post heart attack (as opposed to the 75mg approved by the FDA label). Plainly, a sales representative charged with promoting Plavix® to Akron City Hospital *could not* meet the sales growth quotas set by Defendants without promoting Plavix® off-label.

136. As described more fully below, Partner A has direct and independent personal knowledge of the extent to which the Fraudulent Marketing Scheme has focused on promoting Plavix® off-label for (i) patients who have undergone a coronary artery bypass graft; (ii) patients who suffer a stroke, transient ischemic attack or any cerebrovascular event; (iii) primary

prevention; (iv) as part of diagnostic catheterizations in patients who have not suffered an acute coronary event; and (v) specific sub-populations.

137. Partner A estimates that as much as forty percent (40%) of all Plavix® use within her former sales region is outside the bounds of the drug's FDA-approved label, and that the majority of off-label users are Government Program beneficiaries, especially Medicare beneficiaries.

A. SANOFI FAILED TO TIMELY DISCLOSE, AND THEN DEFENDANTS SOUGHT TO MISREPRESENT, DATA THAT SHOWS PLAVIX® HAS DRAMATICALLY REDUCED EFFICACY FOR A SIGNIFICANT PORTION OF THE PATIENT POPULATION.

138. Pursuant to Section 505 of the FDCA, 21 U.S.C. § 355, and 21 CFR 314.81, Sanofi, as the original applicant for approval to market Plavix® in the United States, has been required to submit annual reports to the FDA that include, among other things: (i) "[a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling" of Plavix®; (ii) [r]eports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties" of Plavix®; and (iii) published clinical trials of [Plavix®] (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety . . . conducted by or otherwise obtained by [Sanofi, as the applicant]." 21 C.F.R. 314.81(b)(2). The purpose of this requirement is to enable the FDA to determine whether there is or may be grounds to withdraw or modify its approval of a new drug application.

139. Further, drug companies are required by law to report adverse events, including "any failure of expected pharmacologic action." 21 C.F.R. § 314.80 (governing post-marketing reporting of adverse drug experiences). Although the original version of this regulation required a report of "any *significant* failure of expected pharmacologic action" (emphasis added), the

FDA amended the regulation in 1989 to delete the word "significant" because it "consider[ed] any report of failure of a drug to produce the expected pharmacological action to be significant." 54 Fed. Reg. 28,872 at 28,889 (July 10, 1989). The FDA also concluded that by deleting the word "significant" from the regulation, it thereafter "would unambiguously require that *all reports of a therapeutic failure (lack of effect)* be submitted to FDA." *Id.* (emphasis added). The public policy objective behind the change was clear: "[A] complete picture of adverse drug experiences, rather than selected reports, [would] improve the [FDA's] ability to determine whether it should take regulatory action." 57 Fed. Reg. 17,950 at 17,983 (Apr. 28, 1992. As applied to this case, a loss or failure of efficacy represents a complete failure of the "expected pharmacologic action" that Sanofi was required to report to the FDA.

140. From the outset, Sanofi knew or should have known that a significant percentage of patients was genetically predisposed to have substantially diminished or no responsiveness to Plavix®. Sanofi was required by law to disclose this information to the FDA but, in concert with the other defendants, it failed to do so because it knew that disclosure would lead to a reduction in the number of prescriptions being written for Plavix® and, consequentially, a decline in sales and revenue.

141. And, when the adverse efficacy data for Plavix® became publicly known to physicians and patients through other channels, Defendants illegally – and without any foundation in fact – promoted that data as a basis upon which physicians should prescribe *greater* quantities of Plavix® to affected patients, leading to even greater, unjustified reimbursements by Government Programs (as well as patients and private insurers) as well as increased risk of serious medical risk to patients.

142. As a consequence of Defendants' deception, numerous patients were put at risk, and Government Programs were made to reimburse myriad false claims for useless prescriptions.

1. As early as 1994, Sanofi knew or should have known, but failed to disclose, that a significant portion of the population is genetically predisposed to having diminished or no responsiveness to Plavix®.

143. When Sanofi submitted its new drug application for Plavix® in 1997, it relied on a remarkably small data set and claimed that it did not fully understand how the drug was metabolized. Sanofi disclosed that it knew only that the drug was required to be metabolized to its active form in the liver, and that three particular enzymes – identified as CYP2B6, CYP2C19 and CYP3A4 – are predominantly involved. These enzymes are part of the cytochrome P450 (CYP) system. Despite not knowing fully how the drug was metabolized, the FDA approved Plavix® for marketing in November 1997.

144. Plavix® is a pro-drug that requires activation in the liver predominantly via the cytochrome P450 enzyme CYP2C19 in order to bind to the platelet P2Y12 ADP receptor and inhibit platelet activation. The CYP2C19 enzyme, like many of the cytochrome P450 enzymes in the liver, has several genetic polymorphisms which can either decrease or eliminate the enzyme's ability to facilitate the oxidation steps required to activate Plavix®. These DNA variations therefore limit the effectiveness of Plavix® in certain individual patients lacking the appropriate gene coding for the CYP2C19 molecule.

145. The particular genetic polymorphisms of the CYP2C19 gene resulting in reduced function and their prevalence in Caucasian, African and Asian populations, was well described in the literature prior to 1995. The effect of these genetic variations of the CYP2C19 enzyme upon the metabolism of other drugs dependent on this enzyme was also well described in the literature at that time.

146. Therefore, at the time Sanofi submitted its new drug application for Plavix®, there was credible scientific evidence that a significant portion of the patient population contains a genetic anomaly that results in dramatically reduced efficacy of Plavix®, and that a subset of those persons will not respond to Plavix® at all. For these patients, Plavix® will have little or no clinical value. Yet, Sanofi failed to disclose that information to the FDA or to physicians.

147. In 1994, three years *before* Sanofi submitted its new drug application for Plavix®, the Journal of Biological Chemistry published the results of a study, sponsored in part by the U.S. Public Health Service, which concluded that a defect in a cytochrome P450 enzyme identified as CYP2C19 led to impaired metabolism of several drugs. The authors reported that they had developed a "simple" genetic test for the defective allele. *See* S. de Morais et al., *The Major Genetic Defect Responsible for the Polymorphism of S-Mephenytoin Metabolism in Humans*, J. BIOL. CHEM. 269:15419-15422 (1994) (the "de Morais Study"). Since Sanofi either knew at the time it applied for approval to market Plavix® or soon thereafter that the drug was metabolized in the liver and that the CYP2C19 enzyme was predominantly involved, it should have disclosed the findings of the de Morais Study to the FDA; however, there is no indication that it did so.

148. In 2002 and 2003, several published studies established a distinction among responders and non-responders to Plavix® therapy. Individual variations in platelet inhibition after treatment with clopidogrel were first reported in 2002. *See* P. Järemo et al., *Individual variations of platelet inhibition after loading doses of clopidogrel*, J. INTERNAL MED. 252:233-238 (2002) (concluding that Plavix® "evoked platelet inhibition exhibits a considerable individual heterogeneity"). *See also* I. Müller et al., *Prevalence of clopidogrel non-responders among patients with stable angina pectoris scheduled for elective coronary stent placement*, J.

THROMB. HAEMOST. 89:783-7 (2003) (concluding that "a subgroup of patients undergoing [percutaneous coronary intervention] does not adequately respond to [Plavix®], which may correspond to the occurrence of thromboischemic complications"); P.A. Gurbel et al., *Clopidogrel for Coronary Stenting: Response Variability, Drug Resistance, and the Effect of Pretreatment Platelet Reactivity*, CIRCULATION 107:2908-2913 (2003) (concluding that "[i]nterindividual variability in the platelet inhibitory response from [Plavix®] occurs in patients undergoing elective coronary stenting"); D. Soffer et al., *Impact of Angina Class on Inhibition of Platelet Aggregation Following Clopidogrel Loading in Patients Undergoing Coronary Intervention*, CATH. & CARDIO. INTERV. 59:21-25 (2003) (finding "significant interpatient variability in the degree of platelet inhibition" and suggesting "resistance to clopidogrel").

149. Several articles published in 2004 and 2005 confirmed the emerging consensus. *See* J.E. Mobley et al., *Frequency of Nonresponse Antiplatelet Activity of Clopidogrel During Pretreatment for Cardiac Catheterization*, AM. J. CARDIO. 93:456-458 (2004) ("Recent investigations have indicated that 20% to 30% of patients fail to attain platelet inhibition after clopidogrel therapy."); D.J. Angiolillo et al., *Identification of low responders to a 300-mg clopidogrel loading dose in patients undergoing coronary stenting*, THROMB. RES. 115: 101-108 (2005) ("Identification of clopidogrel low responders before intervention appears to be an emerging critical direction for tailoring antiplatelet therapy to ensure a more effective antithrombotic protection in these patients.")

150. Although these studies did not specifically address the CYP system or the CYP2C19 enzyme in particular, Sanofi should nevertheless have complied with its legal obligation to notify the FDA (i) that there was a growing body of evidence that a substantial

portion of the patient population would have diminished or no responsiveness to Plavix®, and (ii) that adverse clinical implications of such responsiveness had been reported.

151. Sanofi also failed to bring this information to the attention of physicians to whom they were actively promoting Plavix®, even as they told them that they were providing them with all the pertinent efficacy and safety information regarding the drug.

152. In 2005, the Journal of the American College of Cardiology published the results of a study – *that received research support from Defendants themselves* – into the responsiveness of 544 individuals to Plavix® therapy. The authors noted that their work had been prompted by "a number of reports" (cited and discussed *supra* ¶ 134) that "dichotomized patients who are treated with [Plavix®] into a minority of 'non-responders' and a majority of 'responders.'" The authors concluded that "there is a very large range of responsiveness to ex vivo testing" in patients treated with Plavix® which, if it corresponds to clinical outcomes, means "it is likely that a small but significant portion of patients are receiving inadequate protection from thrombotic events despite currently standard antiplatelet therapy, whereas a similar proportion may be at higher risk for bleeding complications." *See* V. Serebruany et al., *Variability in Platelet Responsiveness to Clopidogrel Among 544 Individuals*, J. AM. COLL. CARDIOL. 45:246-51 (2005) (hereafter, the "Serebruany Study").

153. Plainly, the reports that prompted the Serebruany Study, as well as the conclusions of the Serebruany Study itself, pointed to significant adverse efficacy data. Having sponsored the Serebruany Study, Sanofi surely was aware of its conclusions, and it should have pursued and reported those conclusions to the FDA and the physicians to whom they were promoting the drug. *See* 21 C.F.R. 314.81(b)(2). However, there is no indication that Sanofi did either of those things. Instead, as described below, Sanofi and the other Defendants continued to

work aggressively to grow the market for Plavix®, and increasing numbers of patients were put at risk.

154. Not long after the Serebruany Study was published, the Journal of the American College of Cardiology published (in February 2006) an abstract that concluded:

> These results indicate that subjects with a CYP2C19*2 allele generate less active metabolite of [Plavix®] and this is associated with a diminished pharmacodynamic response. Variation in CYP-mediated metabolism may be a significant contributing factor to the previously reported inter-patient variability in the pharmacodynamic response to [Plavix®].

See J. Brandt et al., *CYP2C19*2 Polymorphism Contributes to a Diminished Pharmacodynamic Response to Clopidogrel* [abstract], J. AM. COLL. CARDIOL. 47:380A (2006) (the "Brandt Study"). With these conclusions to bolster those of the de Morais and Serebruany Studies, there could be no question after February 2006 that there was significant adverse efficacy data that Sanofi should have reported to the FDA and physicians. However, there is no indication that it did so.

155. Shortly after the Brandt Study was published, the American Society of Hematology published a study in June 2006 whose authors observed that "pharmacodynamic response to [Plavix®] varies widely from subject to subject, and about 25% of patients treated with standard [Plavix®] doses display low ex vivo inhibition of ADP-induced platelet aggregation," and concluded that "response to [Plavix®] was strongly influenced by the CYP2C19 genotypic status." *See* J-S. Hulot et al., *Cytochrome P450 2C19 loss-of-function polymorphism is a major determinant of clopidogrel responsiveness in healthy subjects,* BLOOD 108:2244-2247 (2006); *cf.* J.T. Brandt et al., *Common polymorphisms of CYP2C19 and CYP2C9 affect the pharmacokinetic and pharmacodynamic response to clopidogrel but not prasugrel*, J. THROMB. HAEMOST. 5:2429-2436 (2007) ("common loss of function polymorphisms of CYP2C19 and CYP2C9 are associated with decreased exposure to the active metabolite of

clopidogrel" which is "associated with a diminished pharmacodynamic response"); S.M.G. Smith et al., *Common sequence variations in the $P2Y_{12}$ and CYP3A5 genes do not explain the variability in the inhibitory effects of clopidogrel therapy*, PLATELETS 17(4): 250-258 (June 2006) ("anti-platelet effects of clopidogrel . . . demonstrate wide inter-individual variability and patients with clopidogrel resistance may be at increased atherothrombotic risk"); *see also* P.A. Gurbel et al., *Drug Insight: clopidogrel nonresponsiveness*, NAT. CLIN. PRAC.: CARDIO. 3:387-395 (2006) ("Clopidogrel nonresponsiveness is a consistent phenomenon observed in multiple research studies."). While Sanofi plainly should have reported this adverse efficacy data to the FDA and physicians, there is no indication that it did so.

156. By the end of 2006, it was clear to the scientific community that (i) Plavix® must be transformed into an active metabolite by CYP enzymes in order for it to have the desired anti-platelet effect; (ii) the CYP2C19 enzyme plays an important role in metabolizing Plavix®; (iii) the genes encoding the CYP enzymes are polymorphic, meaning that they contain multiple alleles; and (iv) common alleles of that CYP enzyme genes lead to reduced functionality, and thus diminished or no responsiveness to Plavix®. However, there is no indication that Sanofi brought this information to the attention of the FDA, as was required by the FDCA and applicable regulations, or physicians to whom they were promoting the drug.

157. The rising tide of adverse research continued after 2006, and the state of the science was aptly explained in a January 2009 publication by the New England Journal of Medicine, which concluded:

> Among persons treated with [Plavix®], carriers of a reduced-function CYP2C19 allele had significantly lower levels of the active metabolite of [Plavix®], diminished platelet inhibition, and a higher rate of major adverse cardiovascular events, including stent thrombosis, than did noncarriers.

See J.L. Mega et al., *Cytochrome P-450 Polymorphisms and Response to Clopidogrel*, N. ENGL. J. MED. 260:354-62 (2009) (the "Mega Study"). *See also* F. Sofi et al., *Cytochrome P450 2C19*2 polymorphism and cardiovascular recurrences in patients taking clopidogrel: a meta-analysis*, PHARMACOGENOMICS J. 11:199-206 (2011) ("significant association between the CYP2C19*2 polymorphism and an increased risk of major adverse cardiovascular events in the follow-up"); J.M. Sweeny et al., *Antiplatelet drug 'resistance'. Part 1: mechanisms and clinical measurements*, NAT. REV. CARDIOL. 6:273-282 (2009) ("substantial body of evidence now shows an association between nonresponsiveness to clopidogrel and adverse clinical outcomes").

158. The scope of the problem was confirmed by the 2009 Mega Study, which found that approximately 30% of study participants were carriers of at least one CYP2C19 loss-of-function allele. J.L. Mega et al., *Cytochrome P-450 Polymorphisms and Response to Clopidogrel*, N. Engl. J. Med. 260:354-62 (2009); *cf.* J.M. Sweeny et al., *Antiplatelet drug 'resistance'. Part 1: mechanisms and clinical measurements*, NAT. REV. CARDIOL. 6:273-282 (2009) ("reported prevalence of nonresponsiveness to clopidogrel among patients with cardiovascular disease is between 4% and 34%"). Another study published in 2009 estimated that the CYP2C19*2 loss-of-function allele is even more common among African-American (~33% with at least one copy) and Asian (~51% with at least one copy) populations. *See* A. Shuldiner et al., *Association of Cytochrome P450 2C19 Genotype With the Antiplatelet Effect and Clinical Efficacy of Clopidogrel Therapy,* JAMA 302:849-858 (2009).

159. Based on the foregoing studies and others, it is well established that the effectiveness of Plavix® depends on activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19, and that poor metabolizers treated with Plavix® at recommended (*i.e.,* FDA-approved) doses exhibit higher cardiovascular event rates following

acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI) than patients with normal CYP2C19 function.

160. Unfortunately, it was not until March 2009 that *the FDA notified Sanofi* of "new safety information" that it believed should be included in the labeling for Plavix®. When it approved labeling changes two months later, the FDA wrote to Sanofi:

> This information pertains to the risk addressed in several published reports describing the metabolic pathway of clopidogrel in vivo, investigating factors involved in the bioavailability of its active metabolite, and reporting an increased reporting rate of cardiovascular ischemic events in poor responders to Plavix® (clopidogrel bisulfate).

By this point, of course, this "new safety information" had been available to Sanofi for many years, and it should have been Sanofi that alerted the FDA to the information, and not the other way around.

2. Defendants Concealed Critical Data From Physicians, and Actively Misled Them Regarding the Efficacy of Plavix®.

161. Although there was substantial, credible scientific evidence as early as 1994 that a significant percentage of the population has a genetic defect in the CYP2C19 enzyme that predisposes those patients to diminished (or no) responsiveness to drugs (like Plavix®) that are metabolized in the liver with the aid of that enzyme, and although Defendants certainly knew this fact as early as 2006, they concealed that information from prescribing physicians and their own paid promotional speakers, including Partner B, and instead actively mislead them regarding the efficacy of Plavix®.

162. Partner B – an interventional cardiologist – is both a frequent prescriber of Plavix® and someone who regularly has been paid by Defendants to give promotional talks in support of the drug. Although Defendants have regularly promoted Plavix® to Partner B since it was introduced, and although Defendants have regularly paid and encouraged Partner B to

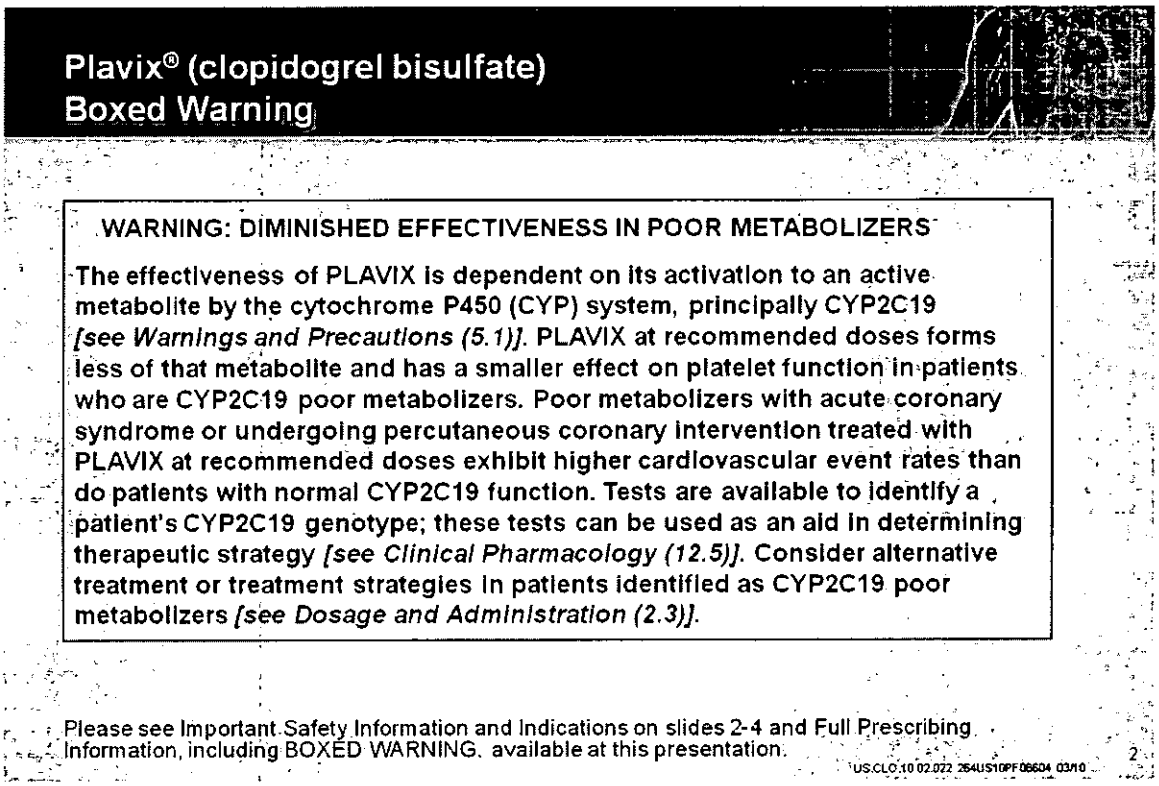
promote Plavix® to other physicians since 2003, Defendants did not disclose the cytochrome P450 responsiveness problem to him until after the Black Box Warning was added to the label, and even then they discounted the issue. And, Defendants did not add any information concerning the cytochrome P450 issue to Partner B's company-provided speaker slides until required to do so by the FDA in 2010. Before then, the information was included only in the Frequently Asked Questions ("FAQs") slides, to be used only if someone in the audience raised a question about the issue, and only because the FDA had told Defendants that they had to add this to the FAQs since there was a Black Box Warning.

163. In fact, when Partner B learned of the adverse literature on this issue on his own in approximately 2006 and repeatedly asked Defendants' employees about it, Defendants continually downplayed its significance and discouraged him from pursuing it further. Defendants effectively prohibited Partner B from discussing the issue with those who attended his programs because there was nothing *in* the company-provided slide deck that would allow him to do so.

164. During his promotional talks, Partner B could not discuss the cytochrome P450 issue unless it was raised by somebody in the audience, in which case he was permitted to respond to the inquiry only after the program had concluded, and only in a one-on-one discussion with the inquiring physician. Still, he was directed to respond to the inquiry by using the company's slide decks that, to the extent they addressed the issue at all, were initially substantively misleading because they minimized and over-simplified the cytochrome P450 problem by, for example, presenting the problem of Plavix® responsiveness as one that tracked a "Normal, Bell-shaped Distribution." This was materially misleading because it was based on "arbitrarily defined" responsiveness cut-off points that lacked any clinical relevance and thus

created the inaccurate impression that hypo- and hyper-responders represented only a small percentage of the overall population.

165. Eventually when required by the FDA to do so the following was included in the slide presentations:



166. Thus, Defendants intentionally left Partner B unprepared and unequipped to provide full, complete, and truthful information about the issue in his paid promotional talks to other physicians, and in so doing they obfuscated the scientific evidence through their paid speaker programs until required to do so by the FDA to fully disclose this information.

167. More recently, Defendants have deliberately attempted to mislead Partner B regarding the state of the science in order to encourage him to continue his promotional and prescriptive efforts on their behalf. Specifically, Partner B began testing his patients to determine their CYP2C19 enzyme gene polymorphisms and platelet responsiveness on Plavix® using the Verify Now P2Y12 platelet assay , and he was shocked to find that between 30% and

40% of his patients had a limited or absent response to Plavix®. When he raised this issue with one of Defendants' sales representatives, Andrea Schoenberg, in mid-September 2011, she first feigned surprise at Partner B's clinical observations, and then asked her manager to contact him to discuss the issue.

168. The district manager seemed surprised as well and stated that this was the first time Defendants had anyone report these kinds of numbers, and then asked a Medical Science Liaison ("MSL"), Ron Joseph, to contact Partner B to discuss his concerns.

169. When MSL Joseph met with Partner B, he initially attempted to avoid any discussion of the issue. When Partner B would not relent, MSL Joseph admitted that Sanofi knew "early on" that the CYP2C19 enzyme was the principle pathway for the activation of Plavix®. MSL Joseph further admitted that, while Sanofi had not been certain in 1997 (when Plavix® was under consideration by the FDA) that CYP2C19 was the principle pathway for activation, it was certain of this by the time of the CURE trial in 2001. However MSL Joseph told Partner B that Sanofi was not aware of the non-responsiveness problem with Plavix® until the publication of independent clinical studies, by "outside" investigators cited in the FDA warnings.

170. Gallingly, MSL Joseph told Partner B that Sanofi did not commission studies to examine the CYP2C19 non-responsiveness problem because it would not have been in its financial self-interest to do so.

171. In any event, MSL Joseph told Partner B that Defendants did not view this as a significant problem, and certainly not a problem for any more than a very small percentage of patients. When Partner B relayed that he was seeing this problem in 30% to 40% of his patients, MSL Joseph deflected these concerns and pointed out that stent thrombosis does not occur in

30% to 40% of patients and therefore the clinical importance of this issue must be minimal. However, discontinuation of thienopyridines and Plavix® non-responsiveness are consistently strong predictors of stent thrombosis and adverse outcomes in multivariate analysis of the data in patients with definite stent thrombosis.

172. Similarly, Defendants have regularly promoted Plavix® to Partner C – the consultative/non-invasive cardiologist – since it was introduced to the market. Further, because Partner C is one of the highest Plavix® prescribers nationally and has a particularly high profile in the medical community, Defendants often assign supervisory/managerial level employees to deliver their promotional pitches directly to him. The following are some of the Sanofi personnel who have promoted Plavix® to Partner C in the manner described in this First Amended Complaint: (i) Andrea Schoenberg; (ii) H.J. Schroeder; (iii) Michelle L. Jenkins; (iv) Sue Sullivan; (v) Jodi Koelsch; (vi) Vanessa Galkin; (vii) Eric MacMillan; (viii) Kenneth J. Langome; (ix) Alma Zakimova; and (x) Anthony Vosilla. The following are some of the BMS personnel who have promoted Plavix® to Partner C in the manner described in this First Amended Complaint: (i) Specialty Senior Business Manager Marian Burke; (ii) Senior Territory Business Manager Craig London; and (iii) Associate Territory Business Manager Gary Pickering.

173. As was the case with Partner B, however, Defendants did not proactively disclose the cytochrome P450 responsiveness problem to Partner C – even as they repeatedly told him that they were providing all the pertinent information regarding Plavix®. Moreover, on numerous occasions, Defendants, through their sales representatives identified *supra*, assured Partner C that there was no variability in efficacy for patients taking Plavix®, and that, to the extent there was a problem at all, it was negligible, even though the overwhelming body of

evidence demonstrated that as much as 30% of Plavix® patients had reduced (or no) response to the drug. Thus, Partner C was left to discover the true scope of these serious, treatment altering, problems on his own.

174. And even then Defendants denied that the tests that were available to determine whether the drug was working for particular patients were validated or clinically appropriate; instead, they deflected Partner C's concerns by telling him that the only valid testing was genetic testing, which they argued was "not clinically appropriate" due to the time and cost involved in such testing.

3. Defendants responded to evidence of diminished patient reactivity by encouraging physicians to prescribe off-label *higher* doses of the drug.

175. Once it became clear that a segment of the population was genetically predisposed to diminished (or no) responsiveness to Plavix®, Defendants sought first to preserve their market share, and then to use the issue to actually expand their market share.

176. For example, when Partner C learned of the CYP2C19 problem through his own review of available scientific literature in approximately late 2008 during an American College of Cardiology Foundation meeting (at a presentation by Dr. Valentin Fuster and in discussions then and shortly thereafter with other attendees and colleagues), he began to question Defendants' sales representatives and supervisors who promoted the drug to him about the scope and substance of the issue. Rather than tell him the truth, they falsely told him the problem was not significant, that it impacted only a small number of patients and that the data likely was skewed by extraneous factors, such as interactions with other drugs, patient failure to take Plavix® as prescribed, and physician failure to prescribe Plavix® for a long enough period of time. According to Partner C, Defendants' sales representatives and supervisors identified *supra* went to great lengths to *challenge* and *obfuscate* the scientific literature in order to allay his

concerns regarding variability of response and implications for the usage of Plavix®. Thus, Defendants misled Partner C and other physicians into believing that their patients' failure to respond to treatment was due to their underlying disease, rather than genetic non-responsiveness to Plavix®.

177. For her part, Partner A has personal knowledge that, when the label for Plavix® finally was amended in 2009 (at the FDA's insistence) to reflect the cytochrome P450 problem, Defendants instructed their combined sales force to downplay its significance. For example, Partner A was instructed to discourage physicians from switching patients to Effient® (prasugrel) – a competitor drug that does not depend on CYP2C19 and that had just been approved by the FDA in July 2009 – by telling them:

> Importantly, there is no clinical evidence or direction in either the PLAVIX® label or my competitor's label that would recommend or even suggest that PLAVIX® patients be switched to their antiplatelet agent.

Of course, such a statement strains credulity, for if a patient is not responding to Plavix® because of a cytochrome P450 problem, the drug may be having little more than a placebo effect on them such that switching to therapy with Effient® would, in most cases, be the logical next step. Further, Defendants trained their sales force to obfuscate the issue on the basis that variability of response among individuals was "potentially attributable" to many factors other than genetic predisposition, including patient noncompliance and inadequate dosing, implicitly suggesting that physicians should address diminished response by counseling their patients and/or increasing their dosage.

178. Moreover, cynically, Defendants responded to the adverse efficacy data by proactively encouraging physicians, including Partner B, to prescribe *higher* or *double doses* of Plavix® to affected patients, telling them that higher doses would counteract the diminished functionality of the patient's CYP system enzymes. For example, MSL Ron Joseph at one point

after the release of Effient® delivered a plainly promotional sales pitch to Partner B in which he specifically encouraged Partner B to double the loading and maintenance doses of Plavix® as a result of the OASIS-7 trial comparing standard Plavix® dosing with increased dosing at thirty days post PCI stent placement. This was central to MSL Joseph's specific promotion of Plavix® in lieu of Effient®, never acknowledging the possibility of diminished or non-responsiveness to Plavix®, and it explicitly was a made of Partner B's speaker training, as MSL Joseph was directing Partner B to deliver the same message during his promotional talks for the company.

179. Defendants' misguided and misleading effort to downplay and obfuscate the cytochrome P450 problem is problematic for three reasons. First, and most obviously, it puts patients at risk by affirmatively misleading physicians regarding the efficacy of the drugs they prescribe for patients in need.

180. Second, it flouts the standard of care for patients who are genetically predisposed to intermediate or poor response to Plavix®. Indeed, the Clinical Pharmacogenetics Implementation Consortium of the National Institutes of Health's Pharmacogenomics Research Network (an assuredly impartial body) recently published *peer-reviewed guidelines* for antiplatelet therapy, and those guidelines specifically and unambiguously *reject* Defendants' effort to encourage physicians to keep all antiplatelet therapy patients on Plavix®. Instead, the Guidelines specifically recommend that intermediate and poor metabolizers *not* be treated with Plavix®, but that they be treated with Effient® or another alternative therapy instead. *See* S.A. Scott et al., *Clinical Pharmacogenetics Implementation Consortium Guidelines for Cytochrome P450-2C19 (CYP2C19) Genotype and Clopidogrel Therapy*, CLIN. PHARM & THERAPEUTICS 90:328-332 (August 2011). These Guidelines should come as no surprise to Defendants, as several of the Guidelines authors are paid consultants for both Sanofi and BMS. *Id.*

181. Third, dosing patients with higher quantities of Plavix® creates a significant risk of *major bleeding complications* and other serious and potentially life-threatening complications.

4. Sanofi's failure to timely notify the FDA and physicians of adverse efficacy data for Plavix®, and Defendants' false and misleading promotion, put patients at risk.

182. Sanofi's failure to timely notify the FDA and physicians of adverse efficacy data for Plavix®, and Defendants' false and misleading promotion, put patients at risk. For example, a study published in the New England Journal of Medicine in January 2009 concluded:

> Among patients with an acute myocardial infarction who were receiving [Plavix®], those carrying the CYP2C19 loss-of-function alleles had a higher rate of subsequent cardiovascular events than those who were not. This effect was particularly marked among the patients undergoing percutaneous coronary intervention.

See T. Simon et al., *Genetic Determinants of Response to Clopidogrel and Cardiovascular Events*, N. ENGL. J. MED. 360:363-375 (2009).

183. Similarly, in January 2009 The Lancet published a study that examined 259 patients who survived a first myocardial infarction and were treated with Plavix® for at least a month in order to assess whether the CYP2C19*2 polymorphism affected long-term prognosis of patients who were chronically treated with Plavix®. The authors concluded:

> [O]ur study shows a strong relation between the presence of the CYP2C19*2 allelic variant and recurrent thrombotic coronary events in clopidogrel-treated patients predominantly of European ancestry who survived a myocardial infarction before 45 years of age.

J-P. Collet et al., *Cytochrome P450 2C19 polymorphism in young patients treated with clopidogrel after myocardial infarction: a cohort study*, THE LANCET 373:309-317 (2009).

184. Others reached similar conclusions regarding the relative safety of treating CYP2C19*2 carriers with Plavix®. *See, e.g.,* D. Sibbing et al., *Cytochrome P450 2C19 loss-of-function polymorphism and stent thrombosis following percutaneous coronary intervention*, EUR.

HEART J. 30:916-922 (2009) ("CYP2C19*2 carrier status is significantly associated with an increased risk of [stent thrombosis] following coronary stent placement."); B. Giusti et al., *Relation of cytochrome P450 2C19 loss-of-function polymorphism to occurrence of drug-eluting coronary stent thrombosis*, AM. J. CARDIOL. 103:806-811 (2009) ("The present study provided the novel finding that the 2C19*2 allele of the CYP2C19 gene was an independent risk factor for drug-eluting [stent thrombosis]."); A. Shuldiner et al., *Association of Cytochrome P450 2C19 Genotype With the Antiplatelet Effect and Clinical Efficacy of Clopidogrel Therapy*, JAMA 302:849-858 (2009) ("nonresponsiveness is widely recognized and is related to recurrent ischemic events"). Indeed, "large meta-analyses . . . have shown that CYP2C19*2 carriers treated with [Plavix®] have a higher risk for major adverse cardiovascular events as opposed to non-carriers . . . , and higher risks of stent thrombosis[.]" *See*, S.A. Scott et al., *Clinical Pharmacogenetics Implementation Consortium Guidelines for Cytochrome P450-2C19 (CYP2C19) Genotype and Clopidogrel Therapy,* CLIN. PHARM. & THERAPEUTICS (June 29, 2011) (advance online publication).

185. This problem is exacerbated in the case of patients who use popular over-the-counter proton pump inhibitors ("PPIs"), such as Prilosec® (omeprazole), since some PPIs further inhibit the CYP2C19 gene function such that concomitant use of Plavix® and a PPI by patients with low responsiveness to Plavix® can diminish responsiveness even further.

186. Defendants' sin was thus not merely one of omission, but also one of commission, for they told physicians that they were providing them with all the pertinent data for Plavix®, even as they withheld the unfavorable data regarding the CYP2C19 gene. This put patient lives at risk, because Defendants effectively encouraged physicians, including Partner B and Partner C, to recommend therapies and procedures based on the false belief that Plavix® would provide

adequate anti-platelet protection for their patients. For example, Defendants encouraged Partner C to believe that Plavix® was an appropriate therapy for virtually his entire patient population without need for any platelet function or genetic testing, and that to the extent patients were not responding to therapy, their non-responsiveness was due to patient non-compliance (*i.e.*, not taking the drug as prescribed) or dosing (*i.e.*, not taking enough of the drug).

187. Defendants actively encouraged cardiologists, including Partner B and Partner C, to prescribe Plavix® in conjunction with implantation of drug-eluting stents based on their false and misleading representation that all their patients would benefit from Plavix®. Had Partner B, Partner C and others in their position known that as many as thirty percent of patients would have diminished (or no) responsiveness to Plavix®, they would not have recommended drug-eluting stents as broadly as they did because patients who receive such stents are highly dependent on anti-platelet agents, such as Plavix®.

188. Had physicians been properly informed that Plavix® may not be effective on many of their patients they would have treated them differently. To begin with, the need for an accurate and practical assay of platelet inhibition in patients on Plavix® would have been recognized sooner. While several research laboratory methods that determine the extent of platelet inhibition in patients on Plavix® have been available for decades, they are technically complex, are not widely available, and therefore clinically impractical. Two commercially available tests to determine Plavix® responsiveness in patients have recently been developed and validated.

189. Plavix® responsiveness is largely dependent upon the normal functioning of the CYP2C19 liver enzyme. There is a commercially available DNA blood test to establish definitively whether a patient has the CYP2C19 gene polymorphisms associated with abnormal

Plavix® responsiveness. However, the DNA test results are not immediately available (one to two weeks) and thus cannot be factored into the clinical decision making process in the setting of an acute coronary syndrome or even at the time of an elective PCI with stent placement.

190. Another commercially available assay of Plavix® induced platelet inhibition is the Verify Now P2Y12 assay from Accumetrics. This simple bedside blood test determines the extent of platelet inhibition in patients on a thienopyridine, such as Plavix®. The results, reported as platelet response units (PRU) are available immediately and therefore can be factored into the clinical decision making process. This test has been available for several years. However, only when the significant degree of variability in patient responsiveness to Plavix® and the adverse clinical outcomes associated with Plavix® non-responsiveness became apparent to clinicians did outside researchers finally perform studies to validate the test results thus allowing for meaningful clinical interpretation. Multiple studies have shown that residual platelet responsiveness (PRU greater than 220-240) is significantly correlated with adverse clinical outcomes in PCI-stent patients.

191. Atherosclerosis is a systemic disease effecting arteries throughout the body. It results from a life-long tendency to accumulate plaque in the arterial wall which as it progresses can lead to heart attacks and strokes. The platelet plays an important role in the development of chronic atherosclerosis and in the acute pathophysiology of plaque rupture which causes heart attacks and strokes. Anti-platelet therapy is a critical component of the treatment for atherosclerosis.

192. The treatment of atherosclerotic coronary artery disease falls into three broad categories: (i) medical therapy; (ii) revascularization by percutaneous coronary intervention (PCI) which in the majority of cases involves stent placement; and (iii) surgical revascularization

via coronary artery bypass surgery (CABG). Knowing whether a patient is responsive or non-responsive to Plavix® would have had a significant impact upon the clinical decision making process throughout the years that Plavix® has been available to clinicians.

193. Aspirin is an effective platelet inhibitor. There is a vast body of scientific literature demonstrating the clinical benefits of aspirin therapy in patients with atherosclerosis. Plavix® works to inhibit platelet activation by binding to the platelet ADP receptor (P2Y12). There are several studies demonstrating the clinical benefits of Plavix® in patients with atherosclerotic coronary artery disease, peripheral arterial disease, and cerebrovascular disease. The CAPRIE trial demonstrated the superiority of Plavix® versus aspirin therapy in reducing cardiovascular events in patients with atherosclerosis. *See* CAPRIE Steering Committee, *A randomised, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE)*, THE LANCET 348:1329-1339 (1996) (the "CAPRIE trial"). Plavix® was recommended as a substitute for aspirin in these patients based on the results of the CAPRIE trial. Clearly knowing whether a patient responded to Plavix® appropriately or not would have altered their clinical management and prevented millions of non-responsive Plavix® patients from being taken off aspirin, a safe and effective therapy, and as a result being placed at increased risk.

194. The CURE trial demonstrated the superiority of aspirin and Plavix® versus aspirin alone in reducing cardiovascular events in patients with acute coronary syndrome, discussed *supra*, who were either treated medically, treated with percutaneous coronary intervention or with coronary artery bypass surgery. *See* The Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators, *Effects of Clopidogrel in Addition to Aspirin in Patients With Acute Coronary Syndromes Without ST-Segment Elevation*, N. ENGL. J. MED. 345:494-502

(2001). Dual anti-platelet therapy with aspirin and Plavix® benefited patients in all three groups. Plavix® received additional FDA approval for the treatment of ACS/UA or ACS/NSTEMI based on the results of this trial. In actual practice, decisions to treat a patient with medical therapy alone or with PCI-stent placement or with coronary artery bypass surgery depend upon a number of variables. Knowing whether a patient responded to Plavix® appropriately or not is a critical variable and would have altered clinical management significantly. Prior to the FDA approval of another thienopyridine, Effient® (prasugrel, FDA approval for ACS with PCI only, 2009) and Brilinta™ (ticagrelor, 2011) the alternatives to Plavix® in non-responsive patients would have been either ticlopidine, a weak thienopyridine platelet inhibitor with frequent hematological side effects and no FDA approved indications, or aspirin. Since patients who are non-responsive to Plavix® who were to be treated medically or with coronary artery bypass surgery would still be on aspirin, they were not necessarily being placed at additional risk. This was clearly not the case for patients treated with percutaneous coronary intervention (PCI).

195. Knowing whether a patient responded to Plavix® appropriately or not would have altered their clinical management and thus prevented millions of non-responsive patients from being placed at increased cardiovascular risk following PCI with stent placement. Since platelet activation is a major factor in the pathophysiology of acute and chronic thrombotic complications following elective or emergent PCI with stent placement, dual antiplatelet therapy with aspirin and a thienopyridine (*e.g.*, Plavix®, Effient®) or Brilinta™ is essential. Knowing whether a patient was responsive or non-responsive to Plavix® prior to having other approved substitutes for Plavix® available would have excluded PCI with stent placement as a treatment option in these patients. The patient would have either been treated medically or treated with coronary artery bypass surgery. Since the FDA approval of Effient® (FDA approval for ACS

with PCI only) and Brilinta™, both of which are effective substitutes for Plavix® that are not effected by any genetic CYP 450 polymorphisms, patients can be initially treated with either one of these medications instead of with Plavix® if testing for Plavix® responsiveness is clinically impractical or the patient is non-responsive to Plavix®.

196. However, by withholding critical efficacy data from the FDA and physicians, Defendants impacted how physicians treated their patients, influencing them to make bad decisions and recommendations to the ultimate detriment of patient safety. Due in part to Defendants' failure to proactively report adverse efficacy data to physicians and to the FDA, as it was required to do, it was not until May 2009 that the FDA approved a revised label for Plavix® that specifically addressed the fact that, due to polymorphisms in the CYP2C19 enzyme, not all patients taking Plavix® will have adequate platelet inhibition.

197. Later in 2009, the FDA required that Defendants add a "WARNINGS" section to the label that specifically described the potential for reduced effectiveness of Plavix® due to impaired CYP2C19 function.

198. And in March 2010, the FDA required that Defendants add a "Black Box Warning" to the label for Plavix®, specifically alerting physicians and patients as follows:

WARNING: DIMINISHED EFFECTIVENESS IN POOR METABOLIZERS ***See full prescribing information for complete boxed warning.***
• **Effectiveness of Plavix depends on activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19. (5.1)** • **Poor metabolizers treated with Plavix at recommended doses exhibit higher cardiovascular event rates following acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI) than patients with normal CYP2C19 function. (12.5)** • **Tests are available to identify a patient's CYP2C19 genotype and can be used as an aid in determining therapeutic strategy. (12.5)**

- **Consider alternative treatment or treatment strategies in patients identified as CYP2C19 poor metabolizers. (2.3, 5.1)**

199. While the addition of this Black Box Warning to the label for Plavix® was a positive development for patient safety, it remains unknown how many patients had been treated with Plavix® before then despite the fact that they were genetically predisposed to low or non-responsiveness.

200. Today, armed with accurate information about Plavix®, Partner C routinely sends his patients for platelet reactivity testing before treating them, as well as during treatment, in order to determine whether they possess the genetic predisposition to low- or non-responsiveness to Plavix®. Through this protocol, he is finding that as many as thirty to forty percent (30% - 40%) of his patients, including those who have been on long-term therapy with Plavix®, are low- or non-responders – a sobering observation since it suggests that, due to Defendants' misconduct – a significant number of his (and other physicians') patients may have been placed at risk.

201. By failing to timely and proactively comply with their legal obligation to alert the FDA and physicians to the fact that a significant portion of the population was genetically predisposed to diminished or non-responsiveness to Plavix®, Defendants unnecessarily placed patients at risk. Had physicians been fully and timely informed not just that a significant segment of the population would have diminished (or no) response to Plavix®, but also that tests were available to determine each patient's genetic predisposition, physicians could have designed alternate therapy regimens that would have been more effective and safer for their patients.

202. It merits some emphasis that Defendants also placed patients at risk by failing to disclose to the physicians to whom they actively promoted Plavix® that a segment of the patient

population would be *hyper-responders* to Plavix®, meaning that they would have a greater tendency to potentially suffer from major bleeding complications as a consequence of Plavix® therapy. However, as with the genetic predisposition to low- or non-responsiveness, Defendants concealed data that showed the variability of patient responses and, until only recently (*see* discussion *supra*), actively encouraged and misled physicians to believe that Plavix® is a "one-dose-fits-all" drug.

5. Sanofi's failure to disclose adverse efficacy data, and Defendants' subsequent effort to counteract that data through off-label promotion, came at the financial expense of patients, private insurers and Government Programs.

203. While patient safety was the primary victim of Sanofi's failure to disclose adverse efficacy data and Defendants' subsequent improper effort to counteract that data, patients, private insurers and Government Programs also paid a hefty economic price for Defendants' misconduct.

204. Defendants knew that, if the FDA and medical community were fully informed that as much as 30% of the patient population was genetically predisposed to have diminished or no response to Plavix®, then physicians would have treated those patients using alternate therapies instead of Plavix®. *See, e.g.,* A. Shuldiner et al., *Association of Cytochrome P450 2C19 Genotype With the Antiplatelet Effect and Clinical Efficacy of Clopidogrel Therapy*, JAMA 302:849-858 (2009) ("Those with the CYP2C19*2 genotype may benefit more from an antiplatelet regimen that does not include [Plavix®], such as the third-generation thienopyridine prasugrel, or ticagrelor and cangrelor."). Even Dr. Deepak Bhatt, principal investigator for the Defendant-funded CHARISMA trial, opined in 2009 that:

> Beyond merely identifying risk, the major reason to perform pharmacogenomic testing [for the CYP2C19 polymorphism] would be to identify patients in whom an alternative antiplatelet approach would decrease ischemic events.

Deepak L. Bhatt, *Tailoring Antiplatelet Therapy Based on Pharmacogenomics*, JAMA 302:896-897 (2009). Of course, if that alternate approach did not include Plavix®, the negative effect on Defendants' sales and revenue could be dramatic.

205. By failing to timely disclose adverse efficacy data for Plavix®, and by subsequently misrepresenting that data, Defendants caused patients and private insurers to pay for vast quantities of a drug that Defendants *knew* would be ineffective for as much as 30% of the patient population.

206. Similarly, Defendants knew from the outset that a significant percentage of patients treated with Plavix® were, and would be, Government Program beneficiaries. (For example, approximately 65% of Partner B's patients are Medicare beneficiaries, and 30% of Partner C's patients are Medicare beneficiaries.) By failing to timely disclose adverse efficacy data for Plavix®, and by subsequently misrepresenting that data, Defendants caused Government Programs to reimburse payments for vast quantities of a drug that Defendants *knew* would be ineffective for as much as 30% of the patient population.

207. Defendants compounded the financial harm to patients, private insurers and Government Programs when they sought to counteract publicity regarding diminished responsiveness to Plavix® by proactively encouraging physicians to *over-prescribe* the drug, using dosing regimens that exceeded the dosing regimen set forth in the FDA-label. This, too, caused financial harm by forcing payors to purchase unapproved – and quite possibly still ineffective – quantities of the drug. Moreover, as the FDA-label for Plavix® explains that there are significant adverse reactions associated with Plavix®, including life-threatening and fatal bleeding, which would be exacerbated by the overdosing that Defendants recklessly promoted.

Indeed, the FDA-label specifically warns that an overdose of Plavix® "may result in bleeding complications."

B. DEFENDANTS HAVE PROMOTED PLAVIX® FOR NUMEROUS OFF-LABEL USES THAT WERE NOT THE ACCEPTED STANDARD OF CARE.

208. Defendants were not content to grow sales of Plavix® simply by failing to disclose critical adverse efficacy data, as described above. Instead, they have taken their scheme a dangerous step further by proactively promoting Plavix® to physicians for numerous uses that have not been approved by the FDA and that are not the medically accepted standard of care. The first step in this second facet of their scheme has been the direct, one-on-one promotion by sales representatives to prescribing physicians.

1. Off-Label Use in Patients Who Have Received a Coronary Artery Bypass Graft

209. A coronary artery bypass graft ("CABG" and pronounced "cabbage") is also known as "coronary artery bypass surgery" or "heart bypass surgery." It is a surgical procedure performed to relieve angina and reduce the risk of death from coronary artery disease. In the procedure, arteries or veins from somewhere else in the patient's body are grafted to the coronary arteries in order to bypass atherosclerotic narrowings and improve blood supply to the heart muscle. Plavix® is not approved by the FDA for CABG patients unless they fit within some other indicated category; however, because the CABG patient population is both significant and susceptible to promotion, Defendants have coveted that market for Plavix®.

210. Defendants' sales representatives, including Partner A, were instructed and encouraged to promote Plavix® for CABG patients generally, and they have done so with great effect. Typically, sales representatives would initiate discussions of the CURE trial in their promotional presentations and discussions with healthcare providers, and they were instructed to, and did, focus the physician's attention on the following passage from that trial:

> In the patients who underwent CABG, the study medication [Plavix®] was restarted after a median of 11 days. Although these interruptions of therapy with the study medication would tend to result in an underestimate of the difference between the clopidogrel group and the placebo group, they also permit us to make useful estimates of the benefits and risks of clopidogrel when it is used routinely and over the long term, as compared with a strategy of more selective and short-term use among those undergoing implantation of a coronary stent.

See The Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators, *Effects of Clopidogrel in Addition to Aspirin in Patients With Acute Coronary Syndromes Without ST-Segment Elevation*, N. ENGL. J. MED. 345:494-502 (2001). The sales representatives then would cite the CURE trial as evidence that Plavix® should be used not just as approved by the FDA, but also in all post-CABG patients.

211. Isabelle Bibet-Kalinyak is one of Defendants' sales representatives who promoted Plavix® in this fashion with the full knowledge and support of her supervisors. She documented some of her efforts in this regard in a "Connect the Dots" initiative she initiated that was, essentially, a form of sales call reporting, in which she identified all the cardiologists in her region by type (*e.g.*, medical, diagnostic, interventional, surgical) and added descriptive notes regarding the doctor's susceptibility to off-label promotion.

212. By promoting Plavix® for all post-CABG patients, Defendants are expanding beyond the drug's FDA-approved label, and thereby exposing a wide range of patients to unapproved uses in a calculated effort to maximize profits.

2. Off-Label Use as Primary Prevention for All Patients

213. One of the more obvious examples of Defendants' illegal over-reaching has been their active promotion of Plavix® for primary prevention, including primary prevention of myocardial infarctions and strokes, in all patients at risk for atherosclerosis. The FDA has not approved Plavix® for primary prevention, and it is not the standard of care. Indeed, generic

aspirin remains the standard of care – at a substantially lesser cost – for patients with atherosclerosis.

214. Defendants have instructed their sales representatives to promote Plavix® for primary prevention, including primary prevention of myocardial infarctions and strokes, and they routinely have done so both aggressively and successfully.

215. Partner A was instructed to promote, and did promote, the fact that a patient's co-pay obligation for Plavix® would, in most circumstances, cost the patient *less* than over-the-counter aspirin. In this respect, Defendants were promoting the drug to primary care physicians for life-long use.

216. Partner B, in his role as a promotional speaker for Defendants, was instructed to promote Plavix® for primary prevention in all patients who had any risk factors for cardiac disease, even in the absence of an on-label diagnosis.

217. Partner C observed that Defendants' promotional strategies were successful, as many patients came to him having already been prescribed Plavix® even though they had not been diagnosed with any on-label diagnosis. For example, Partner C saw many new patients who had been prescribed Plavix® by their primary care physicians based solely on such symptoms and conditions as non-specific EKG changes, atypical chest pain, and putative transient ischemic attack. The frequency with which Partner C saw such patients provides strong evidence that Defendants have successfully promoted the drug for such use.

3. Off-Label Use as Part of Diagnostic Catheterizations in Patients Who Have Not Suffered an Acute Coronary Event

218. Generally, cardiac catheterizations are performed for two reasons: (i) to permit a cardiologist to visually confirm the presence of coronary artery disease, and (ii) to permit a cardiologist to perform a coronary intervention and insert a cardiac "stent" into an artery to

remove a blockage. Thus, cardiac catheterizations may be performed electively to determine the extent of a patient's coronary artery disease, or in an emergent situation when the patient presents with acute coronary syndrome (ACS) with unstable angina, NSTEMI, or STEMI, but only patients in the latter situation fall within the FDA approval for Plavix®.

219. In response to increasing demand for elective catheterizations, cardiac catheterization labs have sprung up around the country. Defendants realized that these clinics would be fertile grounds upon which to promote Plavix®, and so they determined to aggressively promote Plavix® not only to the cardiologists who work at these labs, but also to the cardiologists and general practice physicians who refer patients to these labs. Critically, Defendants have not limited their promotion of Plavix® in this context to patients who suffer from on-label conditions.

220. Instead, Defendants have proactively encouraged all physicians who refer patients for elective catheterization – including general practitioners who are not always qualified to diagnose any on-label condition – to prescribe Plavix® for all patients who receive diagnostic catheterization, whether or not the patient actually suffers from an on-label condition. Defendants also have proactively encouraged the cardiologists who work at these labs to prescribe Plavix® for all their patients who are diagnosed with some degree of heart disease, whether or not the diagnoses fits within the FDA-approved label for Plavix®, and whether or not doing so comports with the prevailing standard of care.

221. For example, Partner A participated along with four sales colleagues and Regional Director Mike Loney in a "CV3" (*i.e.*, regional Plavix® Hospital Team) conference call on August 27, 2010. The subject of the conference call was ticagrelor (Brilinta™, a new competitor drug) and it was led by a Sanofi-aventis employee who carried a Doctor of Pharmacy ("Pharm.D.") degree. At the end of the call, Sanofi District Manager T.J. Smithey (Indianapolis)

discussed a series of promotional slides that he said he could not distribute by email, but that he could discuss on a conference call. Smithey then described his District's successful effort (led by an Evansville, Indiana representative named Petrina Weiss, to persuade the physicians at St. Mary's Hospital and the Ohio Valley Heart Group to establish a "*diagnostic/angiography protocol*" whereby any patient who undergoes catheterization and is diagnosed with confirmed coronary artery disease ("CAD"), or who would be going to an inpatient facility within a few days in order to receive a stent, would be sent home with a one-month supply of Plavix® as a matter of course. According to Smithey, implementation of this protocol led to an immediate five percent increase in Plavix® sales. Sanofi also pursued implementation of 30-day and 9-month protocols (as set forth in the CURE trial) at these cardiac catheterization labs. DM Smithey told the sales representatives on the call that they should learn from his experience and undertake the same promotional efforts in their own sales territories.

222. Partner A was instructed to promote Plavix® in the same fashion DM Smithey had instructed. With the approval and direction of two successive immediate supervisors, Phil Becker and Scott Brousek, Partner A and BMS hospital/specialty sales representative Katrina Cerny promoted Plavix® in the same manner described by DM Smithey to multiple elective catheterization lab managers and opinion leaders, including those at the Outpatient Cath Lab located at 95 Arch Street in Akron, Ohio. All the catheterizations performed at that facility are elective, and Partner A was instructed to (and did) cite American Heart Association/American College of Cardiology guidelines in order to encourage the facility to implement a "diagnostic/angiography protocol" whereby any patient who undergoes an elective catheterization as primary prevention would receive a prescription for Plavix®. The facility declined to implement the protocol, choosing to leave the decision to the discretion of individual

physicians. Accordingly, Partner A and Ms. Cerny, at the instruction of their supervisors, delivered the same promotional pitch to the individual Outpatient Cath Lab physicians, and many of them did employ the protocol.

223. Defendants frequently provided Partner A with coupons and vouchers that she was instructed to provide to the cardiologists at these labs as an inducement to prescribe Plavix®. For example, Partner A was instructed to provide physicians with coupons that would entitle their Medicaid and Medicare patients to receive either a 14-day supply of Plavix® for free, or a $25 discount off of their co-pay for the drug to induce off-label prescribing. "Copayment" is the portion of the cost of an item or service which the Government Program beneficiary must pay. For example, if the Medicare Part D coinsurance is twenty percent of the reasonable charge for the prescription drug, and that charge is $100, the Medicare beneficiary must pay $20 to the pharmacy and Medicare will pay $80.

224. Waiver of copayments by providers, practitioners, or suppliers is unlawful because it results in (i) false claims; (ii) violations of the anti-kickback statute; and (iii) excessive utilization of items and services paid for by Medicare. In certain cases, a provider, practitioner or supplier who routinely waives Medicare copayments or deductibles could also be held liable under the Medicare and Medicaid anti-kickback statute. 42 U.S.C. § 1320a-7b(b). The statute makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid. When providers, practitioners, or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them.

225. Studies have shown that if patients are required to pay even a small portion of their care, they will be better healthcare consumers, and select items or services because they are

medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services.

226. One important exception to the prohibition against waiving copayments and deductibles is that providers, practitioners, or suppliers may forgive the copayment in consideration of a particular patient's financial hardship. This hardship exception, however, must not be used routinely, as is Defendants' practice. Instead, it should be used only occasionally to address the special financial needs of a particular patient.

227. The OIG's concern about potentially abusive waivers of Medicare copayments and deductibles under the anti-kickback statute is longstanding. For example, the OIG has previously stated that providers who routinely waive Medicare copayments or deductibles for reasons unrelated to individualized, good-faith assessments of financial hardship may be held liable under the anti-kickback statute. *See, e.g.*, Special Fraud Alert, 59 Fed. Reg. 65,374 (Dec. 19, 1994). Such waivers may constitute prohibited remuneration to induce self-referrals under the anti-kickback statute and a violation of the civil monetary penalty for inducements to beneficiaries.

228. The OIG's 1994 Special Fraud Alert (*id.*) counsels against the practice of routine waivers of copayments such as the practice employed by Defendants, which specifically targets its Plavix® coupon kickbacks at Medicare and Medicaid beneficiaries. Defendants' not-so-subtle promotion of their copayment assistance to Government Program enrollees includes the same unlawful conduct that the OIG fraud alert concludes is prohibited.

4. Off-Label Use by Patients with Diabetes

229. Another means by which Defendants have sought to improperly expand the market for Plavix® has been through active promotion of Plavix® on the basis that the drug has

shown particular efficacy and safety in specific sub-populations. For example, Defendants' sales representatives have proactively promoted Plavix® therapy to Partner C on the basis that the drug is particularly efficacious for diabetic patients as an adjunct to aspirin therapy.

230. Defendants specifically told Partner C that patients with diabetes routinely should be prescribed Plavix® due to the high prevalence of undiagnosed coronary artery disease among diabetic patients. Indeed, Defendants, through their sales representatives identified *supra*, actively promoted "insulin and Plavix®" for all diabetic patients.

231. However, the FDA has not approved an indication for Plavix® targeting the diabetic sub-population, and it is not the standard of care to treat all diabetic patients with Plavix®.

5. Off-Label Promotion to Counter Effient®

232. Defendants' improper promotion of Plavix® over Effient® was not limited to discouraging physicians from switching patients from Plavix® to Effient® in light of the cytochrome P450 problem discussed *supra*. Rather, Defendants took the additional step of proactively, and improperly, promoting Plavix® as clinically superior to Effient®, including for unapproved uses.

233. As the clinical community slowly discovered that a significant portion of the population is genetically predisposed to diminished or non-responsiveness to Plavix®, Defendants became increasingly concerned that they would lose a sizeable share of the market to Effient®, a competitor drug approved by the FDA in 2009 that did not share the cytochrome P450 problem, and that had been shown by the TRITON-TIMI 38 trial to be superior to Plavix® for the combined endpoint of cardiovascular death, MI, stroke and stent thrombosis. *See* S.D. Wiviott et al., *Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes*, N.

ENGL. J. MED. 357:2001-2015 (2007). Defendants utilized the Plavix® sales force to address this "problem" through off-label promotion.

234. For example, Dr. William Bauman, Director of Cardiac Catheterization Laboratories for the Summa Health System ("Summa"), is a paid speaker for Effient®, and Defendants became aware in 2010 that he was actively encouraging Summa – a high volume cardiac care facility – to implement a new protocol for STEMI patients that would promote Effient®, over Plavix®.

235. Defendants were anxious to block Dr. Bauman's proposed protocol. To that end, with the aid and encouragement of her managers, Partner A and Katrina Cerny (the BMS representative) engaged in a series of off-label discussions with Summa's STEMI coordinator (T.J. Angelis) and Pharmacy Director (Ken Komorny), among others. The purpose of these discussions was to promote Plavix® over Effient®, and Defendants did so by utilizing a variety of off-label sources, including the CURE trial and the ACS/AHA Guidelines discussed *supra*, to argue that Plavix® could be utilized to treat a wider range of patients and a wider range of conditions, both on- and off-label as discussed *supra*, than could Effient®. Defendants' efforts were a success, as Summa's P&T Committee voted down Dr. Bauman's proposed protocol on or about November 22, 2010.

236. Defendants were not content to protect their market position at Summa; they also wanted to expand Summa's utilization of Plavix®. Thus, Defendants, through Partner A and BMS Representative Cerny, actively encouraged the Director of Summa's outpatient Cardiac Catheterization Laboratory (Jon Nichols) to implement a 30-day Plavix® protocol for all patients with confirmed coronary artery disease, notwithstanding the fact that such use is not approved by the FDA.

237. Far from discouraging the plainly improper promotional efforts at Summa Health System, Defendants' managers encouraged such misconduct. Indeed, Partner A's manager at the time, Scott Brosek, told her that he would nominate her for Sanofi's "Plavix® IMPACT US" award based on these specific promotional efforts at Summa.

VIII. THE FRAUDULENT KICKBACK SCHEME

238. The plan and purpose of the Fraudulent Kickback Scheme was to (i) provide free, trade-size "samples" of Hyalgan® to physicians for their commitment to purchase additional quantities of Hyalgan® at commercial rates; (ii) induce physicians to prescribe Hyalgan® and Eligard® by marketing the "spread" between what they would pay to purchase the drug, and what they would be paid by Government and private insurers to prescribe it; (iii) use special "Meeting the Competition" deals to provide steep discounts (including "free" services) for large purchasers; (iv) use speaker programs and other financial incentives to encourage and reward "key opinion leaders" who agreed to promote and prescribe Eligard® off-label; and (v) directly assist and facilitate the reimbursement of off-label claims for Hyalgan® and Eligard® through "free" reimbursement assistance programs (collectively, the "Fraudulent Kickback Scheme").

239. These actions violated the Federal Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b(b), because they were taken to induce customers to buy and prescribe Sanofi's prescription drug products.

240. The Fraudulent Kickback Scheme has been a financial success for Sanofi because it was intended to, and did, result in the purchase and dispensing of Sanofi drug products, including Hyalgan® and Eligard®, and subsequent reimbursement of those purchases by Government Programs. The physicians also profited from this arrangement.

A. SANOFI USES ILLEGAL SAMPLES TO OBTAIN COMMITMENTS TO PRESCRIBE HYALGAN®

241. Since its approval by the FDA in 1997, Hyalgan® has been an expensive drug with a narrow band of approved use. Compounding the challenge of making the drug profitable, it competed against a wide range of similar hyaluronic acid products, including Orthovisc® (Depuy), Synvisc® (Genzyme), Euflexxa® (Ferring), Supartz® (Smith & Nephew), and an array of generic drugs. To the extent each of these products treats the same condition using the same general scientific method, Sanofi found itself having to promote and sell Hyalgan® in a "commodity market" in which it was increasingly difficult to differentiate drugs, so marketing schemes and gimmicks tended to drive market share. Sanofi recognized that sampling could be a very effective gimmick to drive market share.

242. The distribution of prescription drug samples can improperly influence health care professional conduct and negatively impact patient safety. Thus, the Prescription Drug Marketing Act ("PDMA") of 1987 restricts the manner in which pharmaceutical companies may use and distribute samples of their prescription drug products. The PDMA prohibits anyone from selling or billing for a sample, trading or purchasing any drug sample or coupon; delivering prescription drug samples to anyone not licensed to prescribe or to retail pharmacies; and delivering prescription drug samples without a written request from the practitioner.

243. For example, companies such as Sanofi-aventis may not provide drug samples to health care professionals:

(i) if the health care professional intends to seek reimbursement from the Government for the sample;

(ii) if the health care professional intends to use the sample for his or her own personal use; or

(iii) to reward the health care professional for his or her past prescribing habits, or as a financial inducement to encourage future prescriptions.

244. Nevertheless, Sanofi routinely, systematically, and intentionally has engaged in a nationwide, fraudulent kickback scheme by which it provides doctors with free trade-size samples of Hyalgan® in exchange for commitments by those doctors to purchase and prescribe additional quantities of Hyalgan® on a commercial basis. In this manner, Sanofi sought to, and did, improperly influence prescribing and utilization decisions for Medicare, Medicaid and other Government Program beneficiaries throughout the United States.

245. Since at least 2006, Sanof has instructed and required that members of its sales force, including Partner A, distribute free samples of Hyalgan® to a wide array of health care professionals. The sales force was not given any guidance or restriction on the number of samples that they were permitted to distribute or the physicians who could receive them, although sales representatives typically were provided approximately 100 samples per quarter. They were instructed to distribute as much Hyalgan® as was necessary to drive sales growth (irrespective of the FDA-label) and meet their generally unrealistic sales quotas. Thus, the distribution of samples was guided only by the sales representatives' knowledge that if they did not grow sales volume to meet corporate expectations, they would be fired.

246. In fact, Sanofi intended that the sales force would use the free samples to increase Hyalgan® sales volume. Notwithstanding the relatively small on-label patient population for the drug, and its limited on-label dosing regimen, Sanofi issued nearly 737 trade-size, syringe samples (worth some $73,700) to Partner A between December 5, 2006 and October 15, 2008 – an average of approximately 32 samples per month – despite the fact that Partner A was only selling approximately 200-230 syringes per month during that same time period.

247. The following table identifies each of Partner A's "transactions" of Hyalgan 2mL syringe samples between December 5, 2006 and October 15, 2008:

Transaction Date	Type	Lot Number	Qty	Physician Name
12/5/2006	Transfer In	105700	114	
3/4/2007	Shipment Received	112000	100	
4/1/2007	Shipment Received	112000	30	
6/14/2007	Shipment Received	112000	100	
7/16/2007	Transfer In	104400	50	
8/2/2007	Sample Drop	105700	10	Bayrakdar, Ammar
8/2/2007	Sample Drop	105700	5	Ray, Asok
8/3/2007	Sample Drop	112000	10	Murphy, Michael
8/13/2007	Shipment Received	113300	125	
8/16/2007	Sample Drop	105700	5	Behr, Jeffrey
9/7/2007	Sample Drop	105700	5	Kholoki, Mohamed
10/8/2007	Sample Drop	112000	12	Chassin, Eric
10/8/2007	Sample Drop	105700	3	Seymour, Scott
10/17/2007	Sample Drop	105700	15	Lieber, Lawrence
10/24/2007	Sample Drop	105700	5	Bayrakdar, Ammar
11/7/2007	Sample Drop	105700	6	Rezin, Keith
11/12/2007	Sample Drop	105700	5	Zaffer, Syed
11/29/2007	Sample Drop	105700	15	Ahsan, Mohammad
12/13/2007	Sample Drop	105700	5	Freedberg, Howard
12/16/2007	Transfer Out	112000	30	
12/20/2007	Sample Drop	113300	35	Kholoki, Mohamed
1/7/2008	Sample Drop	112000	15	Bayrakdar, Ammar
1/9/2008	Sample Drop	105700	6	Dietz, Frederick
1/9/2008	Sample Drop	113300	5	Green, Christoph
1/16/2008	Sample Drop	105700	6	Rhode, Blair
1/22/2008	Transfer Out	113300	30	
5/28/2008	Sample Drop	113300	20	Kholoki, Mohamed
5/28/2008	Shipment Received	118700	83	
6/1/2008	Loss	104400	54	
6/10/2008	Sample Drop	105700	6	Trotter, David
6/10/2008	Sample Drop	118700	5	Fischer, Calvin
6/24/2008	Sample Drop	118700	15	Green, Christoph
7/14/2008	Sample Drop	118700	3	Lopez, Eugene
7/31/2008	Sample Drop	118700	3	Trotter, David
8/3/2008	Shipment Received	120100	135	
8/12/2008	Sample Drop	105700	10	Dansdill, David
8/12/2008	Sample Drop	120100	6	Dietz, Frederick
8/13/2008	Sample Drop	105700	3	Walker, Marie
8/28/2008	Sample Drop	105700	14	Kholoki, Mohamed
8/29/2008	Sample Drop	105700	6	Mox, Scott
10/7/2008	Sample Drop	105700	15	Schubert, Robert
10/7/2008	Sample Drop	120100	12	Cavalenes, Mark

Transaction Date	Type	Lot Number	Qty	Physician Name
10/15/2008	Transfer Out	120100	95	

248. The Hyalgan® samples that Partner A was given and instructed to distribute were unique because each sample was, in and of itself, an entire initial treatment. Thus, these samples implicitly were not designed for physicians and patients to "test" them before continuing with Hyalgan® therapy; rather, they plainly were inducements to prescribe additional quantities of Hyalgan® in lieu of alternative drugs. Perhaps more alarming, because the samples were trade-size, a physician could, albeit illegally, "sell" the sample to his patient by submitting a claim for reimbursement of the sample's retail price to the patient's insurance payor – which, given the patient population for Hyalgan®, typically was a Government Program.

249. Sanofi, through its local managers, instructed Partner A and others to use the samples to induce physicians to prescribe Hyalgan® through *quid pro quo* agreements, and to reward physicians who already prescribed Hyalgan® in large quantities. Thus, high prescribers of Hyalgan® tended to receive more samples than others, though if the program were run legally the opposite should have been the case.

250. For example, Partner A provided Dr. Mohamed Kholoki, an internal medicine physician located in La Grange Park, Illinois (just outside of Chicago), with numerous free, trade-size syringe samples of Hyalgan® in exchange for his continued use of the drug and his influence over other community physicians who treated osteoarthritis of the knee. Between September 7, 2007 and August 28, 2008, Partner A gave Dr. Kholoki 74 free samples (worth some $100 each or $7400). In return, Dr. Kholoki ordered between 700 and 1,000 syringes of Hyalgan® annually.

251. To repay the favor of his becoming a Hyalgan® "loyalist," Sanofi paid Dr. Kholoki an honorarium to promote Hyalgan® to other physicians. Between March 2007 and late

2008, Dr. Kholoki gave presentations at various events, including community centers, which were attended by patients and physicians alike. During these presentations, Dr. Kholoki touted Hyalgan® as the only hyaluronic acid product he uses for treating osteoarthritis of the knee.

252. Sanofi congratulated Partner A for using free samples as leverage to drive sales. In a March 22, 2007 memorandum authored by Todd Keirns, the Sanofi District Manager for the Chicago District and Partner A's supervisor, the company noted that "Dr. Kholocki (sp) has informed you that he is going through the last of his Supartz and he will be only placing orders for Hyalgan® from now on." Keirns then summarizes Partner A's overall promotional efforts regarding Hyalgan®, noting that Partner A was "doing a good job leveraging things like . . . samples" – a clear acknowledgment of Sanofi's illegal sampling scheme.

253. Sanofi used samples as illegal kickbacks to physicians to maintain their loyalty to Sanofi, not to introduce them to the company's products and features as required in its November 1, 2010 "U.S. Code of Business Conduct: A Prescription for Compliance" (hereinafter "Code of Business Conduct"). For example, in an internal document from January 2006 that summarizes the status of the top five Hyalgan® accounts in the Chicago, Illinois region, the Orthopedic and Arthritis Clinic of Rockford, Illinois was deemed by Sanofi to be "Hyalgan loyalists." Sanofi also acknowledged that Genzyme "was going heavily after the account" with Synvisc®, a competing product to Hyalgan®. In direct response, Sanofi instructed its sales representative to "please keep [the clinic] stocked with Samples." This directive was made in direct contravention of the PDMA's explicit restrictions on the use of samples to leverage sales and was against Sanofi's own Code of Business Conduct.

254. In another example, an October 2006 internal spreadsheet lists Dr. Ammar Bayrakdar, an internal medicine physician from Evergreen Park, Illinois, as using both Hyalgan®

and Orthovisc® in his practice. Importantly, the call notes reflect that "samples are important to doctor." This entry provides a prime example of how Sanofi recognized the importance of using free samples as a method to win business and increase sales, irrespective of the physician's familiarity with the drug. The physician plainly has experience prescribing Hyalgan®, but nevertheless informs the Sanofi sales representative that because he uses competing products, he considers free samples to be "important"—a not-so-subtle suggestion that free product will earn future sales for Sanofi. And Sanofi complied, providing Dr. Bayrakdar with free samples in exchange for his business.

255. Sanofi knew that its samples kickback scheme was illegal. In its own guidance documents, Sanofi explains the Anti-Kickback Act and the type of conduct the law is designed to prevent. For example, Sanofi acknowledges in its Code of Business Conduct that the Anti-Kickback Act "prohibits providing anything of value to a person with the intent to influence that person to recommend or purchase a health care product or service that may be reimbursed by federal healthcare programs, including Medicare and Medicaid." The same Code of Business Conduct (including the version that was given to Partner A as part of her training) explains that, "the law is intended to prevent healthcare decisions that are based on personal gain rather than on what is best for the patient."

256. But Sanofi provided abundant free samples of Hyalgan® to physicians precisely to increase sales of Hyalgan® and thus, Government Program reimbursements in violation of the AKA, 42 U.S.C. § 1320a-7b(b).

257. The Sanofi managers and employees involved in the Fraudulent Kickback Scheme knew that it was illegal to provide free Hyalgan® samples in exchange for physician agreements to purchase additional quantities and/or to influence other physicians to prescribe

Hyalgan®. In fact, Sanofi required its sales representatives to pass a compliance test specifically regarding the use of samples. In a November 16, 2006 email from District Manager Todd Keirns to the sales representatives located in the Chicago, Illinois region, he explains: "DO NOT FORGET, the sample compliance test is due by December 1, 2006. You will have 45 minutes to take the test. Make sure to review the policies and procedures book that was sent to you at the end of October." The test covered the prohibitions against providing an inducement to a Sanofi customer with the intent to influence that person to recommend or purchase a health care product that may be reimbursed by a federal health care program. In addition, the test reinforced the policy that Sanofi employees are prohibited from providing anything to a customer in exchange for any implicit or explicit agreement or understanding to use, purchase, order, recommend, prescribe or dispense any Sanofi product. Nonetheless, in flagrant violation of Sanofi's own stated policies, and the test administered to ensure compliance of those policies, these managers and employees engaged in the practice anyway because they understood that the company's first priority was to promote its products, not comply with the law.

B. SANOFI INDUCES PHYSICIANS TO PRESCRIBE HYALGAN® AND ELIGARD® BY "MARKETING THE SPREAD"

258. A significant component of Sanofi's Fraudulent Kickback Scheme was the manner in which it encouraged physicians to prescribe Hyalgan® and Eligard® in lieu of alternative therapies by telling the physicians that they personally would earn a greater profit on Hyalgan® and Eligard® than the alternatives. Specifically, Sanofi instructed its sales representatives, including Partner A, that they should demonstrate to physicians that the "spread" between the price they would pay to purchase Hyalgan® and Eligard® and the amount they would be reimbursed by Government Programs and other insurers for prescribing it would be greater

than the "spread" available to them for buying and prescribing alternative therapies. Sanofi called this "marketing the spread" and it was highly effective.

259. "Marketing the spread" is an industry term describing the manufacturers' practice of inflating the prices used by Medicare and other federal programs as the basis for reimbursement of the drug, while deeply discounting the price paid by physicians (or giving the drug to physicians for free). The spread is marketed to physicians as a way of increasing their profits when they receive reimbursement for the drug from Medicare and other health programs. This manipulation of the pricing enables pharmaceutical companies to offer doctors kickbacks - *i.e.*, the spread is marketed to doctors as a reason to prescribe that product in preference to a therapeutic equivalent.

260. In order to assist them in "marketing the spread," Sanofi provides its sales representatives with copies of available pricing contracts for healthcare providers in their sales territories. These contracts typically involved purchase volume commitments and associated pricing discounts. Sales representatives are then instructed to promote those contracts to their sales targets by highlighting areas in which the profit margin available to the healthcare provider is greater with the Sanofi drug than it would be if the healthcare provider bought and prescribed a competitor drug.

261. For example, Sanofi sales representative Julie Riley promoted Eligard® to Carol Sather and Ryan Weber of Advanced Urology Associates (Illinois) in an email (with attachment) that included the subject line "Pricing Opportunity" and that stated as follows:

> Great to see you yesterday! Attached is the new agreement we have available for your clinic regarding ELIGARD (leuprolide acetate). The volume commitment they are asking for to receive the low price of $131/MOT is 600 MOTs per calendar quarter. As always, it can be a combination of the 1, 3, 4 & 6-month formulations.

> From what I can tell, your office is using between 600-700 MOTs/quarter of LHRH therapy (and has only increased the last year). So for example, if you are receiving $136 pricing from Watson, the best case scenario is $340,000/year. The cost savings to your practice in taking advantage of this offer would total around $12,500.

(emphasis in original). The fact that this email exists is surprising, since Partner A was instructed to never to put anything on this subject in writing. Instead, Partner A was told that if physicians wanted to discuss the numbers, the physicians should write them down.

262. Plainly, Sanofi was promoting Eligard® over a competitor drug based not on its efficacy or suitability for a particular patient population, but rather on a "pricing opportunity" that would permit the healthcare provider to pocket an additional $12,500 by prescribing Eligard® instead of a competing drug. This was an illegal kickback.

263. In another variation of the "marketing the spread" scheme, Hyalgan® sales representatives, with the knowledge of their supervisors, promoted the drug to physicians by encouraging them to compare the profit they would make through buying and using Hyalgan® against the profit they would make prescribing competing drugs, such as Synvisc®, Orthovisc®, and Euflexxa®. The scheme was to encourage physicians to consider that since Hyalgan® required up to five injections and competing drugs required only three injections, the physician could bill Medicare an additional $152 per patient by prescribing Hyalgan® (*i.e.*, $76 per additional injection) in lieu of a competing drug. For example, in 2007, Partner A, at the direction of Partner A's manager, promoted Hyalgan® in this manner to personnel at Community Orthopedics, a clinic in Joliet, Illinois, and thereby demonstrated to them that even though Hyalgan® was the most costly of the drug class, the additional monies physicians could bill Medicare would offset that cost and ultimately result in greater profit for the clinic. At bottom, however, Sanofi was simply modeling a way for physicians to bill Medicare for additional, unnecessary costs.

C. SANOFI USES "MEET THE COMPETITION" PRICING DEALS WITH PHYSICIANS AS KICKBACKS TO INDUCE PRESCRIPTIONS OF HYALGAN® AND ELIGARD®

264. In addition, Sanofi regularly put together deals on Hyalgan® and Eligard® with packages of discounts for physicians called "Meet the Competition," "Meeting the Competition," or "MTC." The MTC deals allowed sales representatives to lower the net sales price for Hyalgan® and Eligard® in order to compete with the prices of other drugs. These discounts included pricing presentations by the sales representatives concerning how much the price discounts together with the free samples of Hyalgan® and Eligard® were worth in reducing the net price to the physician.

265. Partner A was trained to use MTC deals to secure Hyalgan® and Eligard® business. Indeed, in a ride-along report dated March 22, 2007 Partner A was commended by District Manager Todd Keirns for raising the market shares for Partner A's MTC accounts (the common parlance Sanofi used for physicians who had obtained "Meet the Competition" special pricing concessions). And, sales representatives were regularly provided tracking reports of the MTC deals.

266. Sanofi sales management gave "Negotiation Workshop" training to all sales representatives selling Hyalgan® and Eligard® which specifically emphasized how they were to negotiate MTC deals with physicians. For example, on a conference call held on February 8, 2008, District Manager Michael Bellotto gave the sales team specific instruction on "best practices" in the negotiation of MTC deals with physicians.

267. Not only would Sanofi sales representatives provide steep discounts to "Meet the Competition," they had company-prepared spreadsheets to illustrate how much spread (*i.e.*, profit) the physician could earn by billing these drugs based on the higher list prices or ASP. Sales representatives were trained to "let the doctor do the math," but not leave the spreadsheets

behind. As competitive pressures grew for Hyalgan® and Eligard® sales, in many instances the majority of sales for these drugs were in instances in which Sanofi had offered the physician MTC deals.

268. Here are examples where Partner A completed "Meet the Competition" forms to get spread prices approved by her district manager:

- February 14, 2008. Dr. Mohammed Samer Kholoki, 404 Sherwood Road., LaGrange Park, Illinois 60526. The "Meet the Competition" price of $80 per syringe was approved by District Manager Michael Bellotto. In addition to the $80 per syringe pricing, Dr. Kholoki was given substantial free samples of Hyalgan® described *supra* and further was made a Hyalgan® speaker to retain him as a "Loyal" user of the drug.
- April 1, 2008. Dr. Joseph O'Saben, D.O., Cevene Care Clinic, 6451 E. Riverside Blvd., Suite 103, Rockford, Illinois 61114. The "Meet the Competition" pricing was approved by DM Bellotto. In the year following the MTC deal, Cevene increased its usage of Hyalgan® by some 500%.
- August 3, 2008. Dr. Jeffrey Bear, Rockford Orthopedic Associates ("ROA"), 324 Roxbury Road, Rockford, Illinois 61107. In exchange for ROA's agreement to purchase a minimum of 500 syringes in the next calendar year, DM Bellotto approved a price of $85 per syringe for Dr. Jason Davenport, a Hyalgan® loyalist and speaker.

269. In a variation of the MTC scheme, Sanofi employed "Just in Time" or "JIT" deals for high-volume prescribers of Eligard®. A JIT deal is a contract Sanofi offered to certain customers, which allowed the customer to purchase any amount of Eligard® at a set price. Unlike the MTC deals (which required the physician to order in bulk), a JIT deal the doctor

simply had a volume goal for the quarter. This scheme allowed physicians to order Eligard® "Just in Time" for use.

270. The "Pricing Opportunity" for Eligard® that Sanofi sales representative Julie Riley offered to Advanced Urology Associates (Illinois), discussed *supra*, represented an example of a JIT. Under this particular JIT, the clinic was offered "cost savings" of $12,500 by making a "volume commitment" to purchase Eligard® for the lower price of $131 per month of treatment – a price that was well below the ASP Sanofi reported to CMS.

D. SANOFI INDUCES PHYSICIANS TO PRESCRIBE ELIGARD® BY REWARDING THEM WITH LUCRATIVE, AND SOMETIMES BOGUS, SPEAKING ENGAGEMENTS

271. Sanofi has adopted a sales model that incentivized physicians to prescribe Eligard® by rewarding them with lucrative speaking engagements as a *quid pro quo*. Physicians are active and enthusiastic participants in this corrupt practice. For example, Dr. David Guthman is a urologist in Arlington Heights, Illinois who is known to harass Sanofi sales representatives for multiple paid speaking engagements (at least "one or two" each week) as a *quid pro quo* for prescribing Eligard®. Dr. Guthman even went so far as to tell Partner A in an email that one reason he uses Eligard® is because Sanofi pays him a significant sum through speaking engagements. In that same email, however, Dr. Guthman complained that Sanofi had not paid him as much in speaker fees as it had in the prior year. When Partner A reported this to District Manager Michael Bellotto, Mr. Bellotto told Dr. Guthman that he should not send similar emails in the future. This only caused Dr. Guthman to step up his weekly, verbal harassment of Partner A for additional paid speaking engagements as a *quid pro quo* for additional prescriptions of Eligard®.

272. Sanofi has responded to Dr. Guthman's complaints, harassment of its sales force, and thinly-veiled threats to stop or reduce writing prescriptions for Eligard® by actually

rewarding him with additional paid engagements, even when the company independently determined that it had no business need for them. In some cases, Sanofi set up bogus speaking engagements, *i.e.* unnecessary dinners that Sanofi did not expect anybody other than Dr. Guthman to attend, and that were not attended by anybody other than Dr. Guthman, simply as a mechanism to funnel cash to him so that he would continue to prescribe Eligard®. For example, on October 1, 2008, Sanofi hosted a bogus speaking engagement for Dr. Guthman. The event was held at Tramonto's Steakhouse (Wheeling, Illinois) and the only attendees were the Sanofi sales representative (Partner A) and Dr. Guthman. Although others had been invited, they were invited with the knowledge that they likely would not attend. The bill for this dinner-for-two was $273.22 (which Sanofi fully reimbursed), and Dr. Guthman also collected a speaking fee from Sanofi, even though he gave no presentation. Sanofi held this event not as a means to educate other physicians, but as a means to reward Dr. Guthman's past prescribing behavior and induce future prescriptions.

E. SANOFI OFFERS ILLEGAL REMUNERATION IN THE FORM OF FREE REIMBURSEMENT AND REFERRAL SERVICES TO INDUCE PHYSICIANS TO PRESCRIBE HYALGAN® AND ELIGARD®

1. Sanofi Induces Physicians to Prescribe Hyalgan® and Eligard® By Facilitating the Reimbursement of Claims

273. Sanofi has developed and manipulated its own Medicare and Medicaid reimbursement support services for the express purpose of increasing sales of Eligard® and Hyalgan®.

274. One tool in each Sanofi sales representative's bag was Sanofi's commitment to assist physicians to maximize their reimbursement dollars. Indeed, Sanofi went out of its way to assist physicians to obtain generous reimbursements for prescribing Hyalgan®, even going so far as to distribute a "Hyalgan® Reimbursement Guide" and an "Eligard® Reimbursement Guide"

that were developed as free services to help physicians "receive optimal reimbursement." Sanofi also operated a "HYALGAN® Reimbursement Hotline" and an "ELIGARD® Reimbursement Hotline" to assist physicians with coverage, reimbursement and coding of Hyalgan® and Eligard®, as well as assisting in reversals of denials of coverage.

275. Tellingly, the very first item discussed in the "Hyalgan Reimbursement Guide" is the fact that "Medicare typically reimburses physicians for HYALGAN®," explaining that, as of January 1, 2005, Medicare "will reimburse most drugs based on 106% of the Average Sales Price (ASP)" and that physicians will receive 80% of that amount from Medicare and may bill the patient or secondary insurer for the balance. On the second page of the Reimbursement Guide, Sanofi provides reimbursement guidance specific to Medicaid. Plainly, Sanofi understood that maximizing reimbursement dollars was a key incentive for physicians to prescribe Hyalgan® and Eligard®.

276. And, the Sanofi-distributed Hyalgan® and Eligard® Reimbursement Guides provide important guidance to physicians regarding how their claims for reimbursement should be worded if they are to be paid. For example, the Hyalgan® Reimbursement Guide warns physicians:

> HYALGAN® is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy, and to simple analgesics such as acetaminophen. When filing claims for HYALGAN®, you must indicate an ICD-9-CM diagnosis code indicating the patient's condition.
>
> **715.16** – Osteoarthritis, localized, primary, lower leg
>
> **715.26** – Osteoarthritis, localized, secondary, lower leg
>
> **715.36** – Osteoarthritis, localized, primary/secondary unknown, lower leg
>
> **715.96** – Osteoarthritis, generalized/localized unknown, lower leg

277. Both the Hyalgan® and Eligard® Reimbursement Guides also explain which "Current Procedural Terminology (CPT) codes" should be used to bill for physicians' services in administering Hyalgan® and Eligard®. Both Reimbursement Guides also include a section on "Claims Support and Appeals." That section begins by alerting physicians to the fact that some insurers require a letter of medical necessity to consider coverage of Hyalgan®, and it provides a sample letter for their convenience. The Reimbursement Guides also include a sample "Claims Appeal Letter" in contemplation of the fact that not all claims for reimbursement will be honored upon their submission. In the event that a doctor's office wanted assistance with the appeal of either a Hyalgan® or Eligard® claim denial, Sanofi offered a "free" service to assist physicians' offices.

278. The "free" reimbursement service became a key part of sales representatives' detail to physicians to overcome objections for prescribing Hyalgan® and Eligard®, and it has been a key resource for sales representatives in the promotion of Hyalgan® and Eligard®. Without assistance, reimbursement issues may be costly to physicians in two ways. First, in the event of a denied claim for coverage, a medical practice must bill the patient for drugs already provided. Given the high cost of many of these drugs, patients may be unable to afford payment. If this cost is beyond the patient's means, the practice may then be required to assume the cost of the "buy and bill" drug itself.

279. Second, even in the event that coverage is eventually approved, the process of obtaining that coverage can be costly for physicians and their staffs, requiring time-consuming interaction with payors. Prior authorizations are a payor management tool that most affects therapy utilization. Prior authorizations may be costly for patients as well, requiring them to

postpone treatment until a coverage decision is reached. For all of these reasons, reimbursement concerns have been a frequent physician objection against prescribing Hyalgan® and Eligard®.

280. Such objections were particularly prevalent with regard to drugs like Hyalgan® and Eligard® which are more expensive and no more efficacious than competing drugs. When prescribing less expensive, competing drugs, coverage denials are relatively unlikely, and the reimbursement process is simple and straightforward. However, when prescribing a more expensive, but equally effective, drug, coverage denials are increasingly likely, and the reimbursement process becomes correspondingly more time-consuming and complicated. A physician who writes a prescription for a more expensive drug, and in turn a member of that physician's staff who processes the paperwork, may be required to spend considerable time interacting with the patient's insurance payor or a Government Program, arguing that the particular circumstances of the patient justify coverage of the prescription. The difficulty of arguing the physician's case increases when the alternative therapy is significantly more expensive, as has been the case with Hyalgan® and Eligard®. All else being equal, physicians are inclined to prescribe the cheaper regimen rather than the more expensive drug in order to simplify the reimbursement process.

281. The Office of the Inspector General for the Department of Health and Human Services ("OIG-HHS") has offered its insight on the subject of reimbursement support services, suggesting that such services are highly susceptible to fraud and abuse in Federal Programs, including Medicare and Medicaid.

282. For example, in an advisory opinion issued on October 3, 2006, the OIG responded to an inquiry regarding the propriety of a seller of durable medical equipment ("DME") offering free reimbursement consulting services to some of its customers. *See* OIG-

HHS, Adv. Op. No. 06-16 (issued Oct. 3, 2006). The referenced "reimbursement consulting services" included: (i) general claims submission information, such as advice on how to code products; (ii) reviewing claims; (iii) helping to appeal denied claims; and (iv) providing assistance related to medical justification for receiving particular products. *Id.* at 2. The OIG found that these reimbursement services constituted remuneration and that because the DME suppliers were "in a position to generate Federal health care program business" for the customers, offering such services "clearly" implicated the Federal Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b(b). *Id.* at 4.

283. The OIG further determined that the reimbursement consulting services at issue "would be neither limited in nature, nor free-standing," noting that the free services "would potentially confer substantial independent value upon the DME supplier." *Id.* at 5. The OIG also stated that any assistance "securing Federal reimbursement for individual beneficiaries to receive particular products could cause beneficiaries to receive greater quantities of, or more expensive" product than they actually require. *Id.* In addition, such reimbursement services would tend to provide a financial incentive to steer customers to purchase the supplier's products, "even if products from other manufacturers were less expensive or more appropriate."

284. In this instance, Sanofi's offer of free reimbursement support services causes physicians to prescribe (and patients to receive) the more expensive treatment in the form of Hyalgan® and Eligard®. Also, as the OIG notes, Sanofi's free Reimbursement Programs are being used as financial incentives to persuade physicians to use Hyalgan® and Eligard® despite the fact other products from different manufacturers are equally effective and cheaper. Much like the DME scenario outlined in the advisory opinion, the Hyalgan® and Eligard®

Reimbursement Programs, as the OIG concludes, were simply a "vehicle to pay unlawful kickbacks" to Sanofi's customers in an effort to increase sales.

285. In a second advisory opinion, the OIG determined that any services, including pre-authorization services, that save a physician's office staff time, result in a realization of savings, or which were designed to refer or induce the purchase of a manufacturer's products could constitute unlawful remuneration and thus implicates the anti-kickback statute. *See* OIG-HHS, Ad. Op. No. 10-04 (issued Apr. 30, 2010). The Hyalgan® and Eligard® Reimbursement Programs are specifically designed to influence prescribing and utilization decisions by making it easier and less burdensome for a physician to prescribe Hyalgan® and Eligard® and ultimately obtain reimbursement from Government Programs like Medicare and Medicaid.

2. Sanofi Uses "Free" Persistence Programs as Kickbacks to Persuade Physicians to Prescribe Hyalgan® Long Term

286. In a highly competitive market for hyaluronic acid products, Sanofi devised a scheme through which it offered "free" inducements to physicians to influence their prescribing and utilization habits. For example, Sanofi touts the OsteoArthritis Support and Information Service ("OASIS") to patients as "a FREE program designed for people like you who are currently receiving HYALGAN® treatment and want to do more to manage OA knee pain. OASIS provides information, advice, support and tools that can help. Joining OASIS is part of the joint effort to improve the quality of your care." In reality, however, OASIS is a persistence program, whereby Sanofi induces physicians to prescribe Hyalgan® for long-term use.

287. Under this scheme, Sanofi first induces physicians to prescribe Hyalgan®, in part, because of the free OASIS service. Sanofi's sales representatives were to explain to physicians the benefits from OASIS insofar as the service essentially ensured that the patient would return

in six months to receive retreatment with Hyalgan®, including the accompanying five physician-administered injections, all of which are reimbursable under federal programs.

288. After persuading physicians with the steady revenue stream afforded by OASIS, Sanofi turned its attention to the patient. Specifically, as part of the "free" OASIS program, Sanofi sent letters on behalf of the physicians, informing patients that it had been nearly six months since their last treatment and that it was time to schedule an appointment for more Hyalgan® injections. Sanofi knew that this persistence program would increase sales of Hyalgan® even if other treatment options were more appropriate and/or more cost effective. As part of its OASIS inducement, Sanofi provided patients a free pedometer and exercise bands.

289. Sanofi identified the utilization of OASIS as both a "Business Objective" and a "Strategic Imperative" in its promotional campaign for Hyalgan®. For example, an internal Sanofi spreadsheet reveals that the emphasis on using the free OASIS service was mandated by senior management at the highest levels. Specifically, the document provides that "[a]ll the business Objectives and Strategies are handed down by Marketing and/or Corporate." The first listed Hyalgan "objective" is to "[m]aintain current Hyalgan business and growth within Hyalgan loyalist account with treating early and repeat usage through Oasis." The first listed Hyalgan® "strategic imperatives" was to "relauch [sic] Oasis program/value adds to physician" and to "use Oasis to get retreatments every 6 months."

290. In another example, a January 2007 document entitled "Hyalgan Accounts Top 5: Where are we?" establishes that Community Orthopedics, a clinic in Joliet, Illinois, purchased approximately thirty to forty percent less of Sanofi's products in 2005 than it had the previous year. The clinic was also actively exploring competitor products including Euflexxa®. In an

effort to reverse the downward trend and rejuvenate sales, Sanofi introduced the OASIS program to the clinic as a free service in January 2006.

291. Sanofi went as far as to evaluate overall sales performance, in part, on the extent to which the sales representatives utilized the free OASIS service in their promotional efforts. For example, in a March 22, 2007 evaluation, Partner A's supervisor, District Manager Todd Keirns, analyzed her performance, identifying some achievements and setting goals for the coming year. In discussing Partner A's "utilization of resources," Keirns positively commented that Partner A was "doing a good job of leveraging things like OASIS." Such a statement makes clear that the principal purpose for offering a free service like OASIS was to induce physicians to purchase Hyalgan® and thus increase sales.

IX. SANOFI VIOLATED THE MEDICAID DRUG REBATE PROGRAM, ITS REBATE AGREEMENT(S) WITH HHS, AND THE FEDERAL 340B PROGRAM

292. Sanofi has entered into one or more Rebate Agreements with the Secretary of HHS pursuant to the OBRA 1990 Statute and the Medicaid Drug Rebate Program. That Sanofi has entered into one or more such agreements is confirmed by the fact that it has been issued four Medicaid Pharmacy Rebate Program Labeler Codes: 00024, 00039, 00955 and 63653. Sanofi also has entered into one or more agreements to participate in the 340B Program, described *supra*.

293. Sanofi's "Best Price" is to be calculated "inclusive of cash discounts, free goods, volume discounts, and rebates." *See* Medicaid Sample Rebate Agreement, *available at*, https://www.cms.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf. Thus, Sanofis was obligated to report "free goods" or other discounts or rebates offered to its customers, described herein.

A. SANOFI REPORTED FALSE "BEST PRICES" FOR HYALGAN® AND ELIGARD®

1. Sanofi "Markets the Spread" To Its Customers for Hyalgan® and Eligard® and Fraudulently Reports Its Average Selling Price, Thus Causing Government Programs to Overpay

294. Sanofi has, since the inception of its first Rebate Agreement, been required to accurately report to CMS both its Average Selling Price ("ASP") and Best Price for its products, including Hyalgan® and Eligard®. *See* discussion *supra.*

295. Specifically, over the years, Sanofi has set and controlled the price at which Medicare reimburses physicians for Hyalgan® and Eligard® by reporting inflated ASPs. The ASPs reported by Sanofi have been significantly higher than the sales price the company actually offered to physicians and its other customers. In the case of injectable drugs like Hyalgan® and Eligard®, the ASP is the key metric used to determine how much the Government Programs will reimburse for each prescription. Any unreported discounts would lower the ASP, causing the Government Programs to pay an artificially inflated price to physicians who buy and bill for Sanofi-aventis' drugs.

296. Marketing the spread is material to a drug manufacturer's calculations of its ASP for pharmaceuticals, which is reported to CMS and utilized by the Medicare program, and some of the state Medicaid programs, for reimbursement methodology. Beginning on January 1, 2005, Medicare Part B and some states' Medicaid reimbursement for Hyalgan® and Eligard® in the physician clinic setting was based on a new formula calculated as ASP plus six percent. The regulations governing ASP were promulgated in 2004. *See* 42 C.F.R. § 414.800 *et seq.*

297. When a manufacturer submits its required ASP information to CMS, the manufacturer must certify that the reported ASPs were calculated accurately and that all information and statements made in the ASP submission are true, complete, and current to the best of the company's knowledge and belief and are made in good faith. The company must

further acknowledge that it understands the information contained in the submission may be used for Medicare reimbursement purposes. *See* 42 C.F.R. § 414.805 and Form Addendum B.

298. The calculation of a drug's ASP, which is relied upon by Medicare and some Medicaid programs for calculating reimbursement, must include all price concessions that are not bona fide service fees. *See* 42 C.F.R. § 414.804. The substantial discounts Sanofi offered its customers for both Hyalgan® and Eligard®, as part of its effort to undercut its competitors' pricing, should have been included as price concessions in Sanofi's ASP calculations reported to CMS pursuant to 42 C.F.R. § 414.804(a)(2). Sanofi's failure to include these deep discounts in its ASP calculations for Hyalgan® and Eligard® caused ASPs for both drugs to be over-reported to CMS.

299. For example, with regard to Hyalgan®, Sanofi employs a "meet the competition" pricing scheme in which it first identifies the lowest price offered by its competitors for their hyaluronic acid products and then establishes its own, lower price designed to win customers' business.

300. Specifically, between at least 2006 and 2008, Sanofi sales representatives promoting Hyalgan® in the Chicago area faced heated competition from an international supplier of the drug. Several Canadian pharmacy outlets were offering Hyalgan® to large physician practices in the United States at prices well below market value. And, because the physicians were able to seek reimbursement from federal programs for the ASP reported by U.S. pharmaceutical manufacturers, the difference between the ASP and the price actually paid to these Canadian pharmacies represented a substantial stream of revenue. In some instances, physicians were able to realize a profit of up to $100 per syringe when purchased from one of these Canadian suppliers, as opposed to as little $3 when purchased from Sanofi.

301. In response, Sanofi, using its "meet the competition" model, began to offer Hyalgan® to these large physician practices at steep discounts. According to Partner A, the sales representative would simply have to provide to his/her District Manager (in the case of Partner A, Todd Keirns) a written justification explaining why the lower cost was necessary. The District Manager would then seek approval from the Regional Director (in the case of Partner A, Ambaw Bellette). Once that approval was obtained, the "meet the competition" price was officially offered to the customer.

302. For example, in October 2008, Sanofi sales representative Ryan Collins obtained authorization to offer Hyalgan® to the Illinois Bone & Joint Institute ("IBJI") at a cost of $73 per syringe. In other instances, Sanofi would offer Hyalgan for sale as low as $52 per syringe. In each instance, Sanofi failed to report these substantially discounted amounts to CMS.

303. Sanofi's failure to include these discounts in its ASP calculations resulted in the reported ASPs for Hyalgan® and Eligard® to be inflated. This caused Medicaid programs to be harmed in at least two ways. First, any state Medicaid program utilizing the ASP reimbursement methodology necessarily overpaid for Hyalgan® and Eligard® claims. Second, state Medicaid programs overpaid for dually eligible Medicare/Medicaid beneficiaries where the state Medicaid Programs actually paid as secondary payors.

2. Sanofi's Illegal Sampling Scheme Resulted in False "Best Price" Reports for Hyalgan®

304. As described above, Sanofi's Fraudulent Kickback Scheme resulted in the provision of multiple, large volume free doses of Hyalgan® to its customers. These were not "samples" provided to educate physicians on whether Hyalgan® would be beneficial to their patients' care, as contemplated by the Prescription Drug Marketing Act (*see* discussion *infra*), nor were they provided so that the physicians could simply "try" Hyalgan®. Instead, Sanofi

delivered substantial volumes of Hyalgan® as a *quid pro quo* for physicians' loyalty to the product and/or their efforts to persuade other physicians to purchase Hyalgan®, thereby influencing prescribing or utilization decisions. Sanofi knew that such favorable treatment would lead to greater numbers of prescriptions for its drugs, including prescriptions for Government Program beneficiaries, throughout the United States.

305. None of these physicians were billed or invoiced for these samples.

306. At all material times, Sanofi knew that a substantial number of prescriptions written by physicians were written as a result of Sanofi's Fraudulent Kickback Scheme and would be reimbursed by the Medicaid program and/or 340B entities.

307. The free Hyalgan® that Sanofi provided to its customers should have been included in Sanofi's reported Best Price for these drugs because it provided the drugs free of charge contingent on future purchases and based on influencing other prescribing behavior, thereby causing greater numbers of prescriptions to be written for those products throughout the United States. *See* 42 U.S.C. §§ 1396r-8(k)(1), (c)(l)(C). Section 1927(c)(1)(C)(ii)(I) of the Social Security Act specifies that the reported Best Price must include free goods that are contingent on any purchase requirement.

308. The Best Prices for Hyalgan® that Sanofi did report during the term of its Rebate Agreement(s) were false because they wrongfully omitted the free drugs that were delivered to its customers and were contingent on agreements to make future purchase and influence additional prescriptions for Sanofi's drug products.

B. SANOFI'S FALSE REPORTS CHEATED THE UNITED STATES AND *QUI TAM* STATES OUT OF SUBSTANTIAL SUMS

309. Because Sanofi intentionally reported false Best Prices for Hyalgan® and Eligard®, it wrongfully failed to pay accurate quarterly rebates to each State during each

applicable rebate period. And, consequently, Sanofi wrongfully over-charged Section 340B Program participants for Hyalgan® and Eligard®, and it retained such overpayments.

310. Medicaid did not receive the Best Price (*i.e.*, the "free goods" price) that Sanofi was providing to its customers.

311. Sanofi knowingly (or with reckless disregard for the truth) made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government. Specifically, for the period noted above, and continuing through the present, Sanofi knowingly (or in reckless disregard of the truth) submitted false quarterly statements to CMS of its Best Prices on Hyalgan® and Eligard® to reduce improperly its rebate obligations to the States under the Best Price Program.

312. Sanofi's false quarterly statements of its Best Prices caused the States to submit false and inflated submissions to the Federal Government for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2).

313. Under its Rebate Agreement(s) with the Secretary of HHS, Sanofi was required to certify its compliance with applicable law, including the Medicaid Drug Rebate program. Sanofi's knowing failure to comply renders its certifications false, either expressly or impliedly.

314. By virtue of the false or fraudulent claims that Sanofi knowingly caused to be presented, the United States and the *Qui Tam* States have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

315. The false reports of Best Price by Sanofi trigger liability under the False Claims Act and its state counterparts. Under the Best Price statute, Sanofi was to report its truthful prices to the Secretary, who in turn reported these prices to the States. The States then invoiced Sanofi the amount of Best Price rebates that were owed. Under the False Claims Act and the

State *Qui Tam* counterparts, Sanofi is liable even if it did not make a false statement itself directly to the state "Medicaid agency," so long as a direct or indirect result of their conduct was causing a false statement to be made to the state Medicaid agency.

316. Because Sanofi knowingly, and in reckless disregard for the truth, made false reports of Best Price to the Secretary, the "unit rebate amounts" or "URAs," which represent the products of calculations performed on ASPs and Best Prices which were Sanofi's responsibility to report, also were false. As such, (i) Sanofi knowingly, and/or in reckless disregard for the truth, made, used, or caused to be made or used Best Price or ASP statements or records made to CMS to conceal, avoid, or decrease an obligation to the United States; (ii) the statements or records were false; and (iii) Sanofi knew that the statements or records were false.

317. By virtue of the false or fraudulent claims that Sanofi knowingly caused to be presented, the United States and the *Qui Tam* States have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

X. THE FRAUDULENT MARKETING AND KICKBACK SCHEMES CAUSED THE SUBMISSION OF FALSE CLAIMS TO GOVERNMENT PROGRAMS AND THE *QUI TAM* STATES.

318. The Fraudulent Marketing Scheme served its intended purpose, as it has induced physicians to write both wasteful and off-label prescriptions for Plavix®, and as it has induced the submission of claims for reimbursement of those prescriptions by Government Programs. The Government Programs did, in fact, reimburse those claims for off-label uses.

319. The Fraudulent Kickback Scheme has caused substantial prescriptions of Hyalgan® and Eligard® to be written and submitted for reimbursement by Government Programs. The Government Programs did, in fact, reimburse those claims.

320. At least in part as a result of Defendants' illegal sales and marketing practices, Plavix®, Hyalgan®, and Eligard® have been heavily used for the treatment of Medicaid, Medicare Part B, Medicare Part D, and other Government Program participants.

XI. SANOFI HAS VIOLATED ITS CORPORATE INTEGRITY AGREEMENT

321. As discussed previously, Sanofi is under a Corporate Integrity Agreement (CIA) as a consequence of its September 10, 2007 settlement with the Federal Government arising out of allegations that Sanofi engaged in illegal pricing and promotion of the drug Anzemet®. In that case, the Federal Government alleged that Sanofi had engaged in a scheme to set and maintain fraudulent and inflated prices for Anzemet®, knowing that Government Programs established reimbursement rates based on those prices. In settlement of those allegations, Sanofi agreed as part of the CIA that it would implement stringent controls to ensure that practices like off-label promotion and fraudulent pricing would cease.

322. The CIA also required Sanofi to certify compliance with its terms, and to report any "reportable event," which was defined to include any "matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any federal healthcare program for which penalties or exclusion may be authorized."

323. The CIA notwithstanding, as described more fully above, Sanofi continued its illegal activities at a considerable cost to Government Programs and taxpayers. On that basis, Relator alleges upon information and belief that Sanofi knowingly failed to completely and truthfully certify its compliance with the CIA, and that it failed to completely and truthfully report all "reportable events" in compliance with the CIA. Thus, Relator alleges upon information and belief that Sanofi has knowingly, deliberately and without just cause presented or caused to be presented false certifications or claims under 31 U.S.C. § 3729 *et seq.*

324. As a result of Sanofi's unlawful conduct, the United States has been damaged, and continues to be damaged, by Government Program payments for illegally promoted Plavix®, Hyalgan® and Eligard® prescriptions.

XII. SANOFI HAS VIOLATED THE FALSE CLAIMS ACT BY ITS FALSE CERTIFICATIONS OF COMPLIANCE WITH LAW

325. As a party to a Medicaid Rebate Agreement with the United States Secretary of Health and Human Services pursuant to the Social Security Act, 42 U.S.C. 1396s, Sanofi Labeler Codes: 00024, 00039, 00955 and 63653, as well as various provider agreements, drug products are only eligible for reimbursement if and when Sanofi is in compliance with applicable federal and state laws.

326. These laws include, but are not limited to, the federal and corresponding state anti-kickback statutes, the FDMA and the Food, Drug & Cosmetic Act (and all related regulations). As described in this First Amended Complaint, Sanofi has been and continues to be in violation of the aforementioned laws.

327. Accordingly, Sanofi has, expressly and impliedly, falsely certified its compliance with these federal and state statutes and regulations.

328. Sanofi's false certifications have directly caused Government Programs to pay or reimburse for prescriptions not eligible for payment or reimbursement.

COUNT I
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(A))[1]

329. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

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[1] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(1).

330. Defendants knowingly presented and caused to be presented, and may still be presenting or causing to be presented, to the Government false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(1)(A).

331. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(B))[2]

332. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

333. As a result of Defendants' actions, Defendants knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false or fraudulent claims, records or statements material to the payment of false or fraudulent claims, thereby causing false or fraudulent claims for payment to actually be paid or approved, in violation of 31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B).

334. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Plavix®, Hyalgan®, and Eligard® prescribed to patients enrolled in Government Programs.

335. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

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[2] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(2).

COUNT III
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(C))[3]

336. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

337. As detailed above, Defendants knowingly conspired, and may still be conspiring, with the various health care professionals identified and described herein to commit acts in violation of 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B). Defendants and these health care professionals committed overt acts in furtherance of the conspiracy as described above.

338. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT IV
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(C))[4]

339. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

340. As detailed above, the Sanofi Defendants knowingly conspired with BMS, in part through operation of the BMS/Sanofi Partnership but not only through the BMS/Sanofi Partnership, to commit acts in violation of 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B) with respect to the promotion and sale of Plavix®. The Sanofi Defendants and BMS, including the BMS/Sanofi Partnership, committed overt acts in furtherance of the conspiracy as described above.

341. As a result of the Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

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[3] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(3).

[4] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.*, 31 U.S.C. § 3729(a)(3).

COUNT V
(Violation of California False Claims Act)

342. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

343. This is a civil action brought by Relator, on behalf of the State of California, against Defendants under the California False Claims Act, Cal. Gov't Code § 12652(c).

344. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

345. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

346. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California, or its political subdivisions, in violation of Cal. Gov't Code § 12651(a)(7).

347. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-

related management services for recipients of state and state subdivision funded health insurance programs.

348. As a result of Defendants' actions, as set forth above, the State of California and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VI
(Violation of Colorado Medicaid False Claims Act)

349. Relator incorporated herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

350. This is a civil action brought by Relator, on behalf of the State of Colorado, against Defendants under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306(2).

351. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

352. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

353. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

354. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

355. As a result of Defendants' actions, as set forth above, the State of Colorado and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VII
(Violation of Connecticut False Claims Act)

356. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

357. This is a civil action brought by Relator, on behalf of the State of Connecticut, against Defendants under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301d.

358. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Connecticut, or its political subdivisions, false or fraudulent claims for payment or approval under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(1).

359. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to secure the payment or approval by the State of Connecticut, or its political subdivisions, false or fraudulent claims under a medical assistance programs administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(2).

360. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut, or its political subdivisions, under medical assistance programs administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(7).

361. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

362. As a result of Defendants' actions, as set forth above, the State of Connecticut and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VIII
(Violation of Delaware False Claims and Reporting Act)

363. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

364. This is a civil action brought by Relator, on behalf of the State of Delaware, against Defendants under the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1203(b).

365. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Delaware, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

366. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

367. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 120l(a)(7).

368. The State of Delaware, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the Government of the State of Delaware.

369. As a result of Defendants' actions, as set forth above, the State of Delaware and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT IX
(Violation of District of Columbia False Claims Act)

370. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

371. This is a civil action brought by Relator, on behalf of the District of Columbia, against Defendants under the District of Columbia False Claims Act, D.C. Code § 2-308.15(b).

372. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.14(a)(l).

373. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records or statements to get false claims paid or approved by the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(2).

374. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(7).

375. The District of Columbia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

376. As a result of Defendants' actions, as set forth above, the District of Columbia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT X
(Violation of Florida False Claims Act)

377. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

378. This is a civil action brought by Relator, on behalf of the State of Florida, against Defendants under the Florida False Claims Act, Fla. Stat. § 68.083(2).

379. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Florida or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

380. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida or its agencies, in violation of Fla. Stat. § 68.082(2)(b).

381. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida or its agencies, in violation of Fla. Stat. § 68.082(2)(g).

382. The State of Florida or its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

383. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT XI
(Violation of Georgia False Medicaid Claims Act)

384. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

385. This is a civil action brought by Relator, on behalf of the State of Georgia, against Defendants pursuant to the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.2(b).

386. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

387. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

388. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay, repay or transmit money to the State of Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

389. The State of Georgia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

390. As a result of Defendants' actions, as set forth above, the State of Georgia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XII
(Violation of Hawaii False Claims Act)

391. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

392. This is a civil action brought by Relator, on behalf of the State of Hawaii, against Defendants under the Hawaii False Claim Act, Haw. Rev. Stat. § 661-25.

393. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).

394. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(2).

395. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(7).

396. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

397. As a result of Defendants' actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIII

(Violation of Illinois False Claims Whistleblower Reward and Protection Act)

398. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

399. This is a civil action brought by Relator, on behalf of the State of Illinois, against Defendants under the Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/4(b).

400. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Illinois or a member of the Illinois National Guard, false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

401. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

402. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

403. The State of Illinois, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

404. As a result of Defendants' actions, as set forth above, the State of Illinois has and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIV
(Violation of Indiana False Claims and Whistleblower Protection Act)

405. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

406. This is a civil action brought by Relator, on behalf of the State of Indiana, against Defendants under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-4(a).

407. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(l).

408. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims by the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

409. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

410. The State of Indiana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

411. As a result of Defendants' actions, as set forth above, the State of Indiana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XV
(Violation of Louisiana Medical Assistance Programs Integrity Law)

412. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

413. This is a civil action brought by Relator, on behalf of the State of Louisiana's medical assistance programs, against Defendants under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1.

414. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(A).

415. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

416. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of La. Rev. Stat. Ann. § 46:438.3(D).

417. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

418. As a result of Defendants' actions, as set forth above, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XVI
(Violation of Maryland False Health Claims Act of 2010)

419. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

420. This is a civil action brought by Relator, on behalf of the State of Maryland, against Defendants under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-604.

421. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

422. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

423. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Maryland, or its political subdivisions, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

424. The State of Maryland, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

425. As a result of Defendants' actions, as set forth above, the State of Maryland and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVII
(Violation of Massachusetts False Claims Act)

426. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

427. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 § 5C(2).

428. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).

429. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(2).

430. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).

431. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

432. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII
(Violation of Michigan Medicaid False Claims Act)

433. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

434. This is a civil action brought by Relator, on behalf of the State of Michigan, against Defendants under the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.610a(1).

435. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or

false representations of a material fact in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

436. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).

437. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants were not entitled or in an amount greater than that to which Defendants were entitled, in violation of Mich. Comp. Laws § 400.603(3).

438. Defendants, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly made, presented or caused to be made or presented, and may still be making, presenting, or causing to be made or presented, to an employee or officer of the State of Michigan, or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws §§ 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).

439. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

440. As a result of Defendants' actions, as set forth above, the State of Michigan and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX
(Violation of Minnesota False Claims Act)

441. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

442. This is a civil action brought by Relator, on behalf of the State of Minnesota, against Defendants under the Minnesota False Claims Act, Minn. Stat. § 15C.05(a).

443. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

444. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).

445. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

446. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

447. As a result of Defendants' actions, as set forth above, the State of Minnesota and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XX
(Violation of Montana False Claims Act)

448. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

449. This is a civil action brought by Relator, on behalf of the State of Montana, against Defendants under the Montana False Claims Act, Mont. Code Ann. § 17-8-406(1).

450. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Montana, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

451. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(b).

452. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana, or political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(g).

453. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its governmental entities.

454. As a result of Defendants' actions, as set forth above, the State of Montana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXI
(Violation of Nevada False Claims Act)

455. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

456. This is a civil action brought by Relator, on behalf of the State of Nevada, against Defendants under the Nevada False Claims Act, Nev. Rev. Stat. § 357.080(1).

457. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

458. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

459. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada, or its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).

460. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

461. As a result of Defendants' actions, as set forth above, the State of Nevada and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXII
(Violation of New Jersey False Claims Act)

462. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

463. This is a civil action brought by Relator, on behalf of the State of New Jersey, against Defendants pursuant to the New Jersey Fraud False Claims Act, N.J. Stat. Ann. § 2A:32C-5(b).

464. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an employee, officer or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

465. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

466. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

467. The State of New Jersey, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

468. As a result of Defendants' actions, as set forth above, the State of New Jersey and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII
(Violation of New Mexico Medicaid False Claims Act)

469. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

470. This is a civil action brought by Relator, on behalf of the State of New Mexico, against Defendants under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-7(B).

471. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A).

472. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain false or fraudulent claims under the Medicaid program paid for or approved by the State of New Mexixo, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C).

473. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico, or its political subdivisions, relative to the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(E).

474. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

475. As a result of Defendants' actions, as set forth above, the State of New Mexico and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIV
(Violation of New York False Claims Act)

476. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

477. This is a civil action brought by Relator, on behalf of the State of New York, against Defendants under the New York False Claims Act, N.Y. State Fin. Law § 190(2).

478. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any employee, officer or agent of the State of New York, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

479. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false claims paid or approved by the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(b).

480. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

481. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

482. As a result of Defendants' actions, as set forth above, the State of New York and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXV
(Violation of North Carolina False Claims Act)

483. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

484. This is a civil action brought by Relator, on behalf of the State of North Carolina, against Defendants under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-608(b).

485. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

486. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

487. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina, or its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).

488. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

489. As a result of Defendants' actions, as set forth above, the State of North Carolina and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVI
(Violation of Oklahoma Medicaid False Claims Act)

490. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

491. This is a civil action brought by Relator, on behalf of the State of Oklahoma, against Defendants pursuant to the Oklahoma Medicaid Fraud False Claims Act, Okla. Stat. tit. 63, § 5053.2(B)(1).

492. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Oklahoma, or its political subdivisions false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

493. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

494. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma, or its political subdivisions,, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

495. The State of Oklahoma, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

496. As a result of Defendants' actions, as set forth above, the State of Oklahoma and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVII
(Violation of Rhode Island False Claims Act)

497. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

498. This is a civil action brought by Relator, on behalf of the State of Rhode Island, against Defendants pursuant to the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-4(b).

499. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Rhode Island or a member of Rhode Island's National Guard false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

500. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

501. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit

money to the State of Rhode Island, or its political subdivisions,, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

502. The State of Rhode Island, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

503. As a result of Defendants' actions, as set forth above, the State of Rhode Island and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVIII
(Violation of Tennessee Medicaid False Claims Act)

504. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

505. This is a civil action brought by Relator, on behlaf of the State of Tennessee, against Defendants under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(b).

506. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

507. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false or fraudulent records or statements to get false or fraudulent claims under the

Medicaid program paid for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

508. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

509. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

510. As a result of Defendants' actions, as set forth above, the State of Tennessee and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIX
(Violation of Texas Medicaid Fraud Prevention Act)

511. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

512. This is a civil action brought by Relator, on behalf of the State of Texas, against Defendants under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.101(a).

513. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or

misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment than was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

514. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed — and may still be concealing or failing to disclose, or causing to be concealed or not disclosed — information that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment than was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

515. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of false statementd or misrepresentiond of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).

516. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and may still be making claims under the Medicaid program for services or products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

517. The State of Texas, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

518. As a result of Defendants' actions, as set forth above, the State of Texashas and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXX
(Violation of Virginia Fraud Against Taxpayers Act)

519. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

520. This is a civil action brought by Relator, on behalf of the Commonwealth of Virginia, against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.5(A).

521. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

522. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

523. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

524. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

525. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXI
(Violation of Wisconsin False Claims for Medical Assistance Law

526. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

527. This is a civil action brought by Relator, on behalf of the State of Wisconsin, against Defendants under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(5)(a).

528. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the State of Wisconsin, or its political subdivisions, false or fraudulent claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(a).

529. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made

or used, false records or statements to obtain approval or payment of false claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(b).

530. The State of Wisconsin, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

531. As a result of Defendants' actions, as set forth above, the State of Wisconsin and/or its political subdivisions been, and may continue to be, severely damaged.

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729 *et seq.*; Cal. Gov't Code § 12650 *et seq.*; Colo. Rev. Stat. § 25.5-4-304 *et seq.*; Conn. Gen. Stat. § 17b-301a *et seq.*; Del. Code Ann. tit. 6, § 1201 *et seq.*; D.C. Code § 2-308.13 *et seq.*; Fla. Stat. § 68.081 *et seq.*; Ga. Code Ann. § 49-4-168 *et seq.*; Haw. Rev. Stat. § 661-21 *et seq.*; 740 Ill. Comp. Stat. § 175/1 *et seq.*; Ind. Code § 5-11-5.5 *et seq.*; La. Rev. Stat. Ann. § 46:439.1 *et seq.*; Md. Code Ann., Health-Gen. § 2-601 *et seq.*; Mass. Gen. Laws ch. 12, § 5A *et seq.*; Mich. Comp. Laws § 400.601 *et seq.*; Minn. Stat. § 15C.01 *et seq.*; Mont. Code Ann. § 17-8-401 *et seq.*; Nev. Rev. Stat. § 357.010 *et seq.*; N.J. Stat. Ann. § 2A:32C-1 *et seq.*; N.M. Stat. Ann. § 27-14-1 *et seq.*; N.Y. State Fin. Law § 187 *et seq.*; N.C. Gen. Stat. § 1-605 *et seq.*; Okla. Stat. tit. 63, § 5053 *et seq.*; R.I. Gen. Laws § 9-1.1-1 *et seq.*; Tenn. Code Ann. § 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Va. Code Ann. § 8.01-216.1 *et seq.*; and Wis. Stat. § 20.931 *et seq.*

B. That judgment be entered in Relator's favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a),

plus a civil penalty of not less than five thousand ($5,000) or more than ten thousand dollars ($10,000 per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and § 3730(h), Cal. Gov't Code § 12652(g)(4), Colo. Rev. Stat. § 25.5-4-306(4), Conn. Gen. Stat. § 17b-301e(e), Del. Code Ann. tit. 6, § 1205, D.C. Code § 2-308.15(f), Fla. Stat. § 68.085, Ga. Code Ann. § 49-4-168.2(i), Haw. Rev. Stat. § 661-27, 740 Ill. Comp. Stat. § 175/4(d), Ind. Code § 5-11-5.5-6, La. Rev. Stat. Ann. § 439.4, Md. Code Ann., Health-Gen. § 2-605, Mass. Gen. Laws ch.12, § 5F, Mich. Comp. Laws § 400.610a(9), Minn. Stat. § 15C.13, Mont. Code Ann. § 17-8-410, Nev. Rev. Stat. § 357.210, N.J. Stat. Ann. § 2A:32C-7, N.M. Stat. Ann. § 27-14-9, N.Y. State Fin. Law § 190(6), N.C. Gen. Stat. § 1-610, Okla. Stat. tit. 63, § 5053.4, R.I. Gen. Laws § 9-1.1-4(d), Tenn. Code Ann. § 71-5-183(d), Tex. Hum. Res. Code Ann. § 36.110, Va. Code Ann. § 8.01-216.7, and Wis. Stat. § 20.931(11).

D. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in Cal. Gov't Code § 12651(a), plus a civil penalty of not less than five thousand dollars ($5,000) per claim or more than ten thousand dollars ($10,000) per claim as provided by Cal. Gov't Code § 12651(a), to the extent such multiplied penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each actt, as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 17b-301b(b)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Gen. Stat. § 17b-301b(b)(1), to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Delaware multiplied as provided for in Del. Code Ann. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five- hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act, as provided by Del. Code Ann. tit. 6, §1201(a), to the extent such multiplied penalties shall fairly compensate the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. Code § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each fase claims, as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168.1(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim as provided by Ga. Code Ann. § 49-4-168.1(a), to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in Haw. Rev. Stat. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Haw. Rev. Stat. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1)(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars ($5,000) as provided by Ind. Code § 5-11-5.5-2(b), to the extent such multiplied penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for

in La. Rev. Stat. Ann. § 46:438.6 (B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by La. Rev. Stat. Ann. § 46:438.6 (B)(1), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by La. Rev. Stat. Ann. § 46:438.6 (C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by La. Rev. Stat. Ann. § 46:438.6 (C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Maryland or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Md. Code Ann., Health-Gen. § 2-602(a), multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars ($10,000) for each false claim, pursuant to Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such multiplied penalties shall fairly compensate the State of Maryland or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relator's favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions for the value of payments or

benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Mass. Gen. Laws ch 12. § 5B, multiplied as provided for in Mass. Gen. Laws ch 12. § 5B, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to Mass. Gen. Laws ch 12. § 5B, to the extent such multiplied penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Q. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided, as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Michigan as a result of Defendants' unlawful conduct, as well as not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim, as provided by Mich. Comp. Laws § 400.612(1), as well as the costs incurred by both Michigan and Relator, as provided by §§ 400.610a(9) and 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the Government of the State of Minnesota multiplied as provided for in Minn. Stat. § 15C.02(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Minnesota False Claims Act, as provided by Minn. Stat. § 15C.02(a), to the extent such multiplied penalties shall fairly compensate the Government of the State of Minnesota for losses

resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Mont. Code Ann. § 17-8-403, multiplied as provided for in Mont. Code Ann. § 17-8-403(2), plus a civil penalty of not less than five thousand dollars ($5,00) or more than ten thousand dollars ($10,000) for each false claim, pursuant to Mont. Code Ann. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Nev. Rev. Stat. § 357.040, multiplied as provided for in Nev. Rev. Stat. § 357.040(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act, pursuant to Nev. Rev. Stat. § 357.040(1), to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. Stat. Ann. § 2A:32C-3, plus a civil penalty of not less than and not more than the civil penalties allowed under the federal False Claims Act (31 U.S.C. § 3729 *et seq.*) for

each false or fraudulent claim, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

V. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. Stat. Ann. § 27-14-4, multiplied as provided for in N.M. Stat. Ann. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

W. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 189(1), plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) for each false claim, pursuant to N.Y. State Fin. Law § 189(1), to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relator's favor and against Defendants for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.C. Gen. Stat. § 1-607,

multiplied as provided for in N.C. Gen. Stat. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. Gen. Stat. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in Okla. Stat. tit. 63, § 5053.1(B), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by Okla. Stat. tit. 63, § 5053.1(B), to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. Gen. Laws § 9-1.1-3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by R.I. Gen. Laws § 9-1,1-3(a), to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tenn. Code Ann. § 71-5-182, multiplied as provided for in Tenn. Code Ann. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than twenty-five thousand dollars ($25,000) pursuant to Tenn. Code Ann. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tex. Hum. Res. Code Ann. § 36.052(a), multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to Tex. Hum. Res. Code Ann. §§ 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

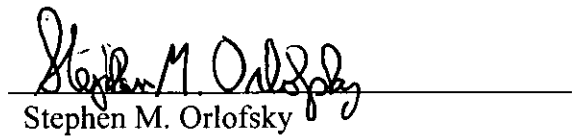
DD. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in Wis. Stat. § 20.931(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Wis. Stat. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

EE. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

FF. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit; and

GG. That Relator be granted such other and further relief as the Court deems just and proper.

W. Scott Simmer *(admitted pro hac vice)*
Alan M. Freeman *(admitted pro hac vice)*
Andrew M. Miller *(to be admitted pro hac vice)*
BLANK ROME LLP
600 New Hampshire Avenue
Washington, D.C. 20037
Telephone: (202) 772-5800



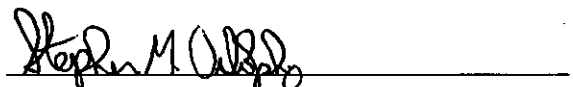
Stephen M. Orlofsky
Nicholas C. Harbist
David C. Kistler
New Jersey Resident Partners
BLANK ROME LLP
A Pennsylvania LLP
301 Carnegie Center, 3rd Floor
Princeton, NJ 08540
Telephone: (609) 750-7700

Counsel for Plaintiff/Relator
JKJ Partnership 2011 LLP

Dated: April 4, 2012

JURY TRIAL DEMAND

Relator demands a trial by jury of all issues so triable.



Stephen M. Orlofsky
Nicholas C. Harbist
David C. Kistler
New Jersey Resident Partners
BLANK ROME LLP
A Pennsylvania LLP
301 Carnegie Center, 3rd Floor
Princeton, NJ 08540
Telephone: (609) 750-7700

W. Scott Simmer *(admitted pro hac vice)*
Alan M. Freeman *(admitted pro hac vice)*
Andrew M. Miller *(to be admitted pro hac vice)*
BLANK ROME LLP
600 New Hampshire Avenue
Washington, D.C. 20037
Telephone: (202) 772-5800

Counsel for Plaintiff/Relator
JKJ Partnership 2011 LLP

Dated: April 4, 2012

LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiff/Relator JKJ Partnership 2011 LLP hereby certifies that, to its knowledge, the matter in controversy in this action is not the subject of any other pending lawsuit, arbitration, or administrative proceeding.

W. Scott Simmer *(admitted pro hac vice)*
Alan M. Freeman *(admitted pro hac vice)*
Andrew M. Miller *(to be admitted pro hac vice)*
BLANK ROME LLP
600 New Hampshire Avenue
Washington, D.C. 20037
Telephone: (202) 772-5800

Stephen M. Orlofsky
Nicholas C. Harbist
David C. Kistler
New Jersey Resident Partners
BLANK ROME LLP
A Pennsylvania LLP
301 Carnegie Center, 3rd Floor
Princeton, NJ 08540
Telephone: (609) 750-7700

Counsel for Plaintiff/Relator
JKJ Partnership 2011 LLP

Dated: April 4, 2012